



Angix® Digital Angiography System

Pre-Installation Manual



DOC1732089 - Angix III Pre-Installation Manual

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1 SYMBOLS



WARNING! Check attached documentation (when in the equipment);
WARNING! (when in the manual)

2 INTRODUCTION

This manual has as its objective to provide support during the preparation works for the installation of **Angix III Angiography and Hemodynamics System**.

The GE provides support during the preparation works for the installation, from orientations regarding electrical installation to the equipment layout sketch in the area where it will be installed.

The guidelines described in this manual must be followed in order to gather the best performance and safety during the operation of the set and to avoid problems during the equipment installation and operation.

2.1 Important notes



The whole infrastructure, electric installation, and other needs for the equipment installation is full responsibility of the client.



In case of difficulties in the implementation of the guidelines, please get in touch with the XPRO Customer Support Center for study and guidance regarding appropriate solutions.



XPRO will not be held responsible for problems caused by the non-execution of the equipment installation according to the instructions and/or documents provided thereby.



XPRO will not be responsible for problems caused by the non-execution of the equipment installation according to the applicable regulations and/or by unauthorized personnel.



2.2 Technical Specifications

2.2.1 Equipment information

Characteristics	Angix® III
Brand:	XPRO Sistemas Ltda.
Product:	Angix® Digital Angiography System III
ANVISA Registration No.:	80260940003
Module:	Mechanical System
Operation mode:	Continuous operation with intermittent load
IEC Class:	Class I Equipment
IEC Type:	Type B Equipment
Protection level	IPX0
Equipment usage in the presence of anesthetic mix with air, oxygen, or nitrous oxide.	Inappropriate
Operating conditions:	+18 to +28 degrees Celsius
	30 to 70 % of humidity without condensation
	525 to 795mm Hg pressure
Transport and storage conditions	-25 to 70 degrees Celsius
	5 to 95% of humidity without condensation
	375 to 795 mm Hg pressure
Standards	NBR IEC 60601-1 – General rules for the safety of electro-medical equipment.
	NBR IEC 60601-1-2 – Collateral rules of electromagnetic compatibility.
	NBR IEC 60601-1-3 – Protection against radiation from X-ray apparatus for diagnosis.
	NBR IEC 60601-2-28 – Private prescriptions applicable to source-sets of X-rays and to emitting-sets of X-ray for medical diagnosis.
	NBR IEC 60601-2-32 – Safety of equipment associated with X-Ray equipment.
	NBR IEC 60601-2-43 – Specific requirements for the safety of X-Ray equipment for interventionist procedures.
	NBR ISO 9000:2000 – Quality Management Systems – Requirements
Statements of Conformity	“Associated radiologic equipment Angix Table, NBR IEC 60601-2-32:2001”
	“X-RAY EQUIPMENT WITH RADIOLOGIC PROTECTION, as of NBR IEC 60601-1-3:2001”
	Interventionist X-Ray Equipment “ANGIX III Digital Angiography System”, ABNT NBR IEC 60601-2-43:2004.



2.2.2 Electric Specifications

<i>Characteristics</i>	<i>Angix® III</i>
Maximum power	5,5 kVA(stand by) 110 kVA (during radiation trigger)
Supply	380V 3N~
Supply operating range	+/-10% (342 to 418V~)
Frequency	50 - 60 Hz +/- 5%
Required input power	110 kVA (with load reserve, including the Póllux® High Volta Generator)
Primary protective device	80A thermomagnetic breaker

<i>Characteristics</i>	<i>Póllux® High Voltage Generator</i>
Maximum power	80 kW (800mA @ 100kVp @ 10ms)
Average consumption	3 kW/h (during the examination)
Primary protective device	80A thermomagnetic breaker

2.2.3 Technical characteristics

<i>Characteristics</i>	<i>Angix® III</i>
Craniocaudal view	45° CRA and 50° CAU ($\pm 0.5^\circ$)
RAO / LAO View	+/- 125° ($\pm 0.5^\circ$)
Distance of the focus of the tube to the image Intensifier	90 cm to 118 cm (± 1 cm)
Table top height	80 cm to 106 cm (± 1 cm)
Isocenter	108 cm (± 1 cm)
Dimensions of the radiation detector	9" or 12"(Image intensifier) and 20 x 20 cm (plan detector)
Top Length	288 cm
Top Width	60 cm (± 0.5 cm)
Maximum Table Load	200 kg (patient) + resurrección massage + 50kg of accessories per track
Total equipment mass	2200 kg (including generator)
Total arc mass	750 kg
Total table mass	400 kg
Total mass of monitor support	150 kg (including monitors)
Equipment shelf life	10 years



2.2.4 Reference standards for infrastructure (Installation in Brazil)

- It is highly recommended that, in some cases, the party responsible for the infrastructure of the angiography and hemodynamics service compulsorily complies with the prescriptions of the following standards and regulations listed below:
 - Resolution RDC 50/2002 ANVISA – Technical Regulations for the planning, programming, elaboration, and evaluation of physical projects of Health Assistance Establishments ('EAS') (EAS);
 - NBR 5410 – Low voltage electrical facilities; NBR 5419 – Structural protection against atmospheric discharges;
 - NBR 7256 – Treatment of air in Health assistance Establishments ('EAS') – Requirements of project and execution for installation.
 - NBR 13534 – Electrical facilities in health assistance establishments – Safety requirements;
 - NBR IEC 60601.1 – Electro-domestic equipment – Parte 1 – General safety prescriptions.

Observation:

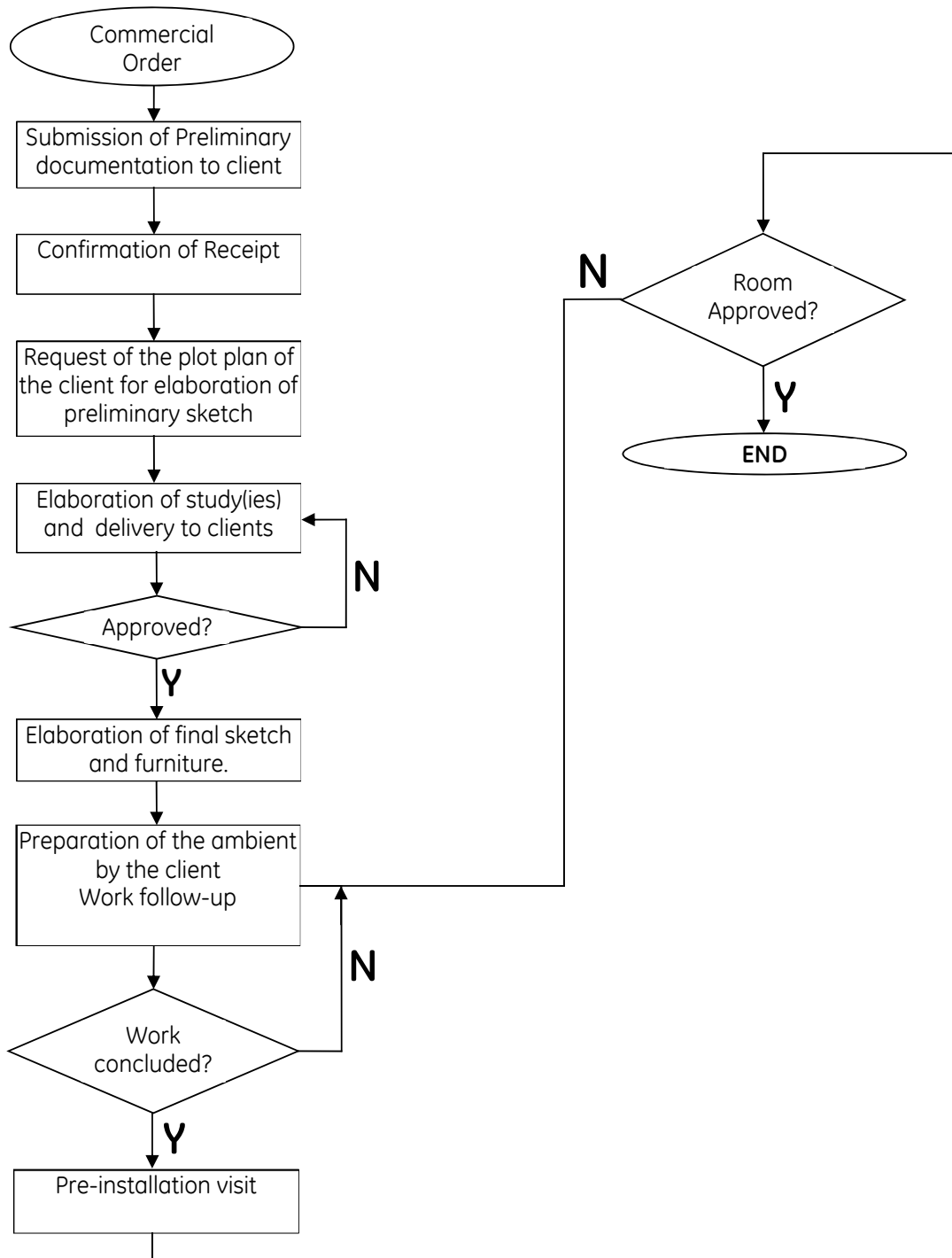
- For the installation in other countries, the respective local regulatory agencies shall be consulted for the obtainment of the applicable rules on hospital infrastructure, including those related to radiologic protection.
- Always look for the up-to-date versions of the reference standards with the respective agencies of issue.



3 INSTALLATION GUIDELINES

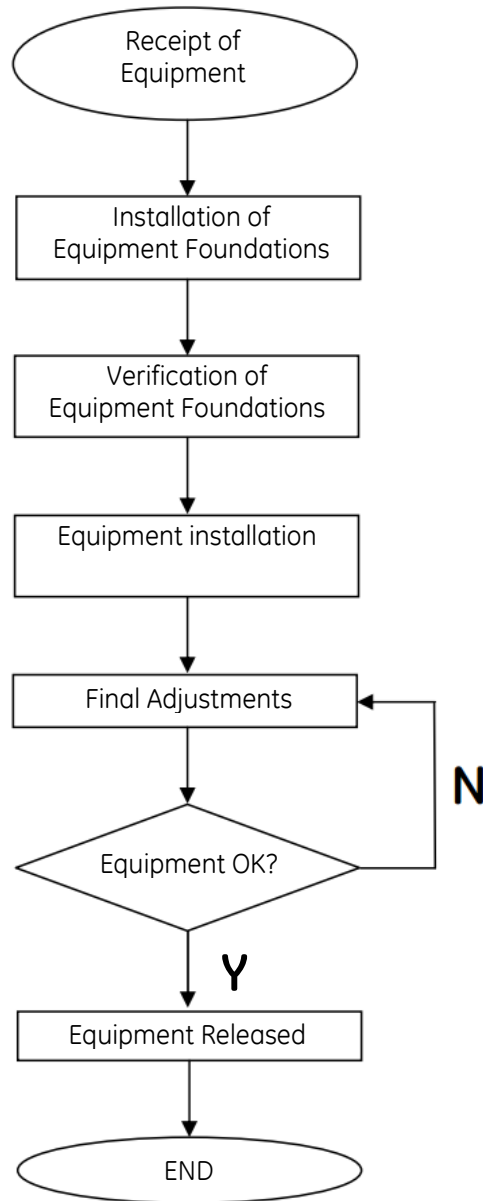
3.1 Installation Flowcharts

3.1.1 Room preparation process flowchart.





3.1.2 Equipment installation process flowchart





3.2 Electric installation

3.2.1 Technical standards for electric network and grounding

- For the execution of the electric network and grounding, the guidelines contained in the technical standards listed below shall be observed, including the particularities related to electrical installations for X-ray equipment:
 - NBR 5410 – Low voltage electrical facilities;
 - NBR 13534 – Electric installations in health assistance establishments – Safety requirements;
 - NBR IEC 60601.1 – Electro-Medical Equipment – Part 1 – General safety prescriptions.



The non-execution of the grounding according to the applicable rules and/or by unauthorized personnel may generate faults and undue equipment operation, which, in extreme cases, may cause serious and even lethal injuries to the patient and operator.



XPRO will not be held responsible for problems caused by the non-execution of the grounding according to the applicable regulations and/or by unauthorized personnel.

3.2.2 Electric network

- The electric network of supply to the equipment must be in compliance with the standards mentioned by item 3.2 - Electric installation of this manual, and shall also meet the following items:
 - A load of 110 kVA must be reserved for the proper equipment installation;
 - The minimum power cable gauges must be observed, as of Table 3.2.2-1-.

Table 3.2.2-1-Electric network

Gauge (mm ²)	Maximum length (m)
35	40
50	60
70	80
95	110
120	140
150	170
200	185



- For other distances, please consult the power cable manufacturer.
- The equipment must be connected preferably to a network from a dedicated transformer or with the purpose of supply to similar equipment (X-ray generators), as to avoid mutual interference to the equipment connected to the power source;
- Proceed with the identification of the characteristics of the electric network as follows:
 - Number of transformers at the substation;
 - Operating voltage of the transformer(s) existing at the substation (primary and secondary);
 - Power available at the transformer(s);
 - Existence of other equipment with power greater than 50kVA and connected to such transformer(s);
 - Possibility of installation of a dedicated breaker for the Hemodynamics equipment;
 - Existence of a generator group supplying the transformer(s). In form in which transformer it will be connected;
 - Power of the generator group, if any;
 - Hospital total demand.
 - For electric networks with substantial oscillations and instability, please use a no-break homologated by GE, as to ensure the operation of Angix within the operation limits;
 - Whenever the use of No-Break is necessary, an autotransformer shall be used at its output as to ensure equipment protection;



The unavailability of sufficient load for the equipment operation may generate faults and undue operation, which, in extreme cases, may cause serious and even lethal injuries to the patient and the operator.



XPRO will not be held responsible for problems caused by the non-execution of the electric network according to the applicable regulations and/or by unauthorized professionals.



3.2.3 Room Lighting

- The room shall have two types of lighting:
 - Fluorescent source, in order to provide lighting for general use.
 - Incandescent lighting. This type shall preferably contain two independent controls, one to regulate the intensity over the work area of the physician and the other to the area of auxiliary work.
 - Switches must be inside the examination room.

3.2.4 Surgical Light

- A small surgical light shall be installed next to the examination table, with switch next to the lighting switches of the room and cabling all the way to the ceiling, as of the location indicated in Figure 3.3.21-2.
- The surgical focus is provided by customer.

3.2.5 Auxiliary Sockets

- Sockets for the provision of power to the support equipment must be provided, with voltages of 127 and 220 VAC, with ground pin as of National Standard NBR 14136.
- The sockets must be identified in relation to the voltage in order to avoid accidents of equipment energization.
- The number and the position of the sockets must be provided following Table 3.3.21-1 – Sockets Table.
- The auxiliary sockets must be connected to the network of the clinic, all with 2 pins + ground and 4" x 4" boxes.
- The grounding of sockets shall be the same of the magnetic switch.

3.2.6 Internet connection

- Broad band Internet connection shall be provided exclusively for the control room.
- The GE counts on remote a support system that allows the safe conduction of preventive maintenance and corrective maintenance (adjustments, settings, calibrations), and software updates. This allows more speed in onsite maintenances, since the technician arrives at the location with the identified fault and, during remote preventive maintenances, faults may be verified even before the equipment shutdown. We will provide onsite a Workstation Firewall to ensure connection security, avoiding unauthorized access and ensuring the reliability of the studies information.
- Prerequisites for remote access:
 - Internet exclusively for the GE equipment;
 - Broad band Internet service with minimum upload speed of 150kbps and download of 256kbps;



- Inform GE by mail, fax or e-mail (xpro.service@ge.com) the data below: Internet provider:
- Type of connection, Login and Password.
- The Internet information shall be provided 20 days before the expected start-up of the installation.

3.2.7 Grounding and Power

- Grounding must follow the recommendations by the standards mentioned in item 3.2.1 of this manual.
- See the equipment grounding map, according figure 3.2.7-1.
- See the equipment power map, according figure 3.2.7-2.
- The electric installation shall have TT grounding scheme, as of item 3.2.1 of NBR 5410 and item 5 of NBR 13534.
- At the installation, the grounding of supply (neutral) must be provided in separate from the equipment mass grounding (as of NBR 5410).
- The TT scheme is in compliance with the requirements of the standards mentioned above and offers a better electrical protection against electric shock to the patients and equipment operators.
- The grounding shall be located in convenient location, the nearest possible to the equipment and preferably in area subject to rain and easy to access by the inspection, such as gardens, open areas, etc.
- The grounding should be have maximum impedance of 5 Ohm and should be to the equipment.
- Use a cable with green/yellow identification.
- The minimum gauge of the Ground cable shall be dimensioned according to the section of the phase cables, as of Table 3.2.7.1 - Grounding:

Table 3.2.7-1 - Grounding

Phase cable sections (mm ²)	Min. Ground cable sections (mm ²)
35	25
50	25
70	35
95	50

- For different phase cable sections, please obey the following ratio:

$$Btm = (S / 2)$$

- Where:
Btm = Minimum gauge of Ground Cable;
S = Phase cables gaug



Figure 3.2.7-1

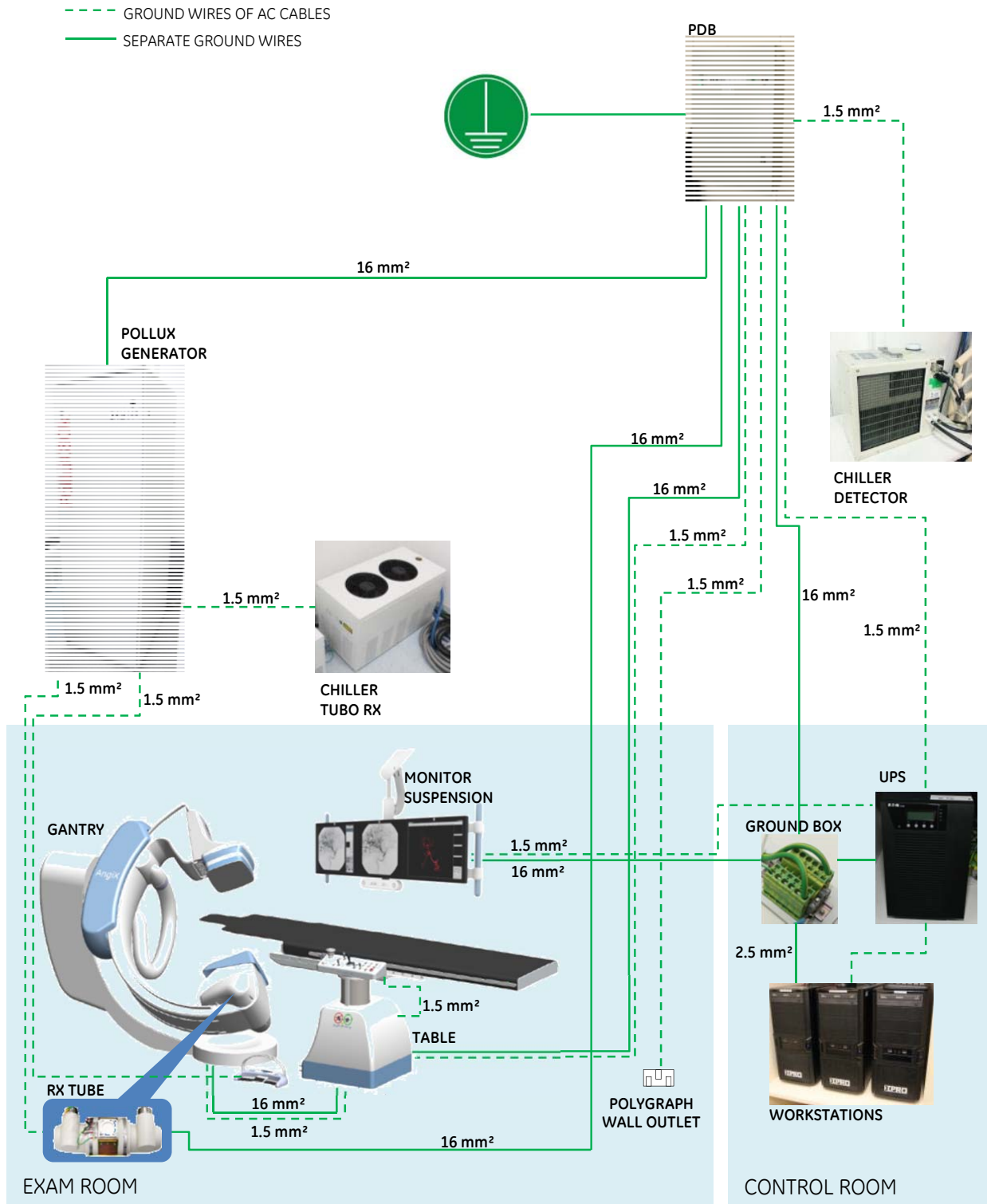
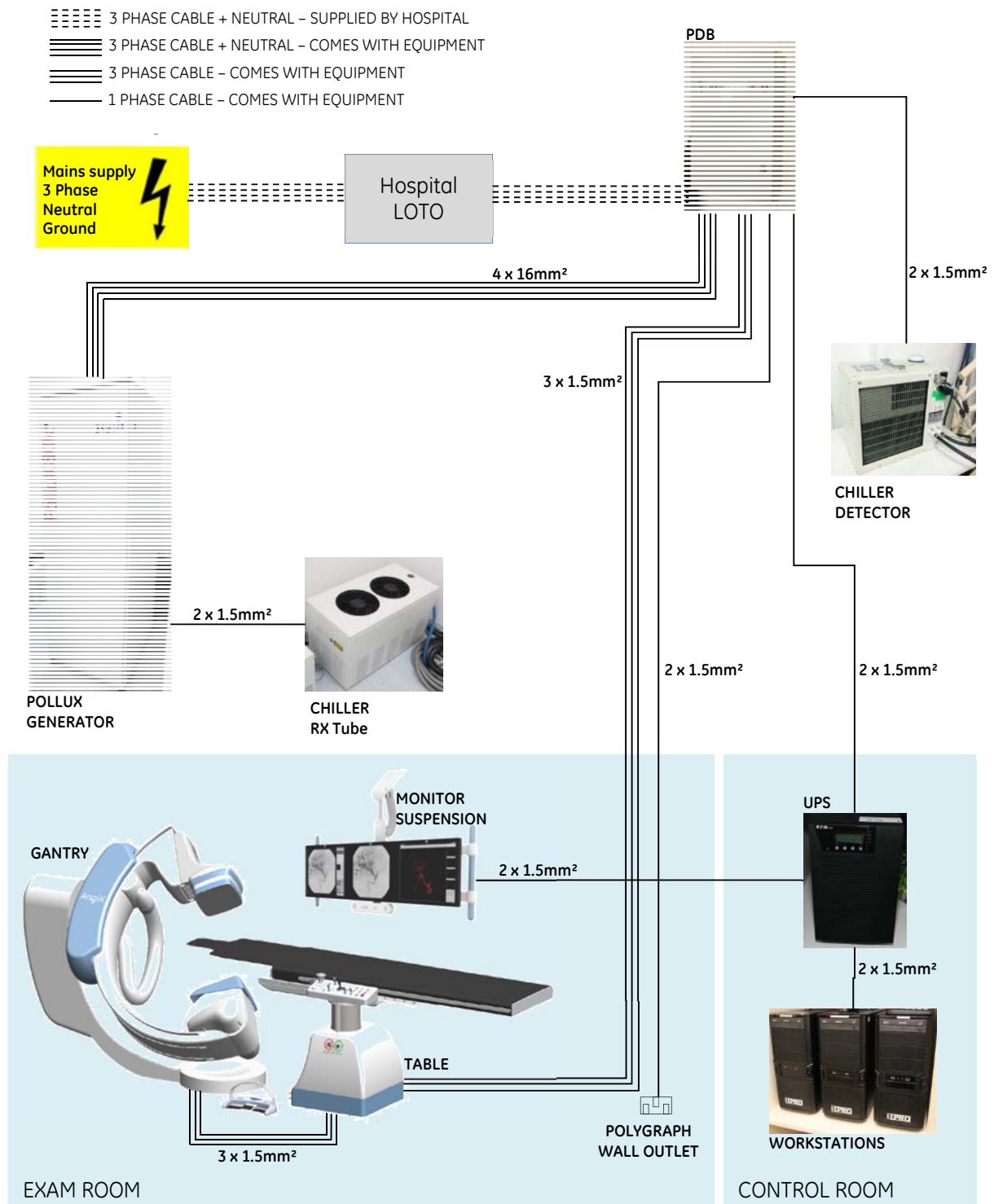




Figure 3.2.7-2



NOTE: ALL SHORT AC POWER CABLE LESS THAN 3 METERS, BETWEEN PERIPHERALS AND RESPECTIVE POWER STRIP, ARE NOT SHOWN. ALL HAVE A SINGLE PHASE LINE, A NEUTRAL LINE AND A GROUND WIRE



3.2.8 Risk of Interference

- The equipment may generate interference to other equipment, thus requiring the use of a network from a dedicated transformer or with the purpose of supplying similar equipment.



3.3 Installation of Fixing

3.3.1 Installation area

- A minimum area of 30 m² must be considered for a comfortable installation, with dimensions of approximately 6 x 5 meters for the examination room.
- For the control room the minimum suggested area is of approximately 8 m², with approximate dimensions of 3 x 2.7 meters.

3.3.2 Structural reinforcements

- It is necessary to reinforce the floor and slab for supporting the concentrated loads of the deck, arc base, and monitor support base.
- Base of the gantry / Base of the table: structural reinforcements for 1,600 kgf (1,400 Kgf of the equipment plus 200 Kgf of the patient) and 50 MPa Traction Concrete.
- The minimum floor concrete thickness shall be of 20 cm, being recommended that the ironwork is 18 cm from the upper portion of the floor for the installation of anchors.
- Base of the monitor support: structural reinforcement for 150 kgf.
- These reinforcements may be of reinforced concrete or of metallic structure, usually of easy execution.

3.3.3 Gantry / Table Bases

- The Bases must be anchored to the floor, and leveled as of item □.
- The positioning of the base shall be according to the pre-installation sketch provided by XPRO.
- Important criteria for securing the base:
 - Leveling
 - Position
 - Alignment with the finished floor

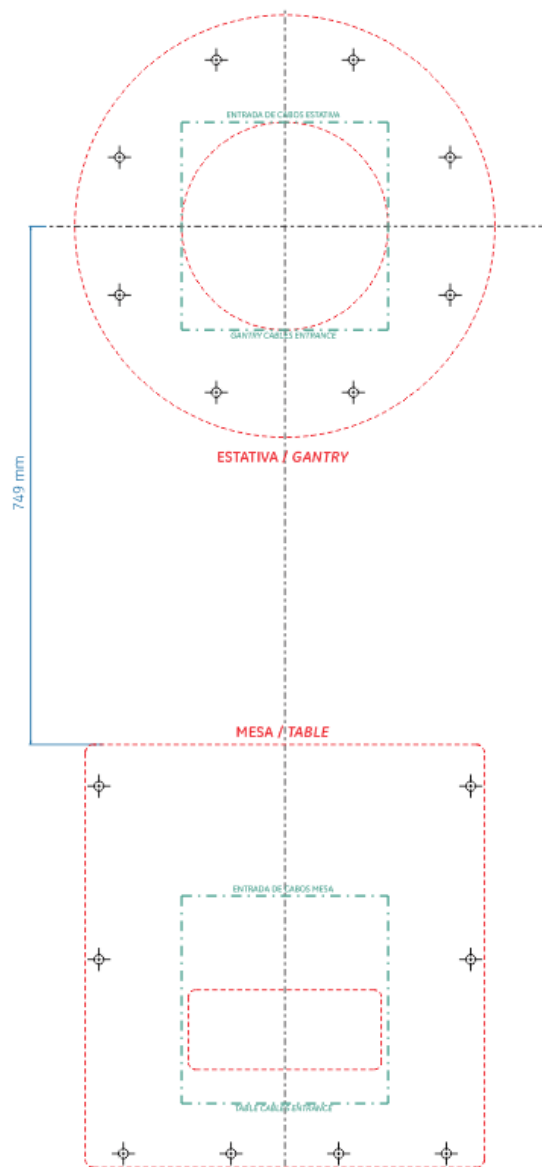
3.3.4 Preparation for the installation of bases

- The preparation for the installation of the bases of Angix in the examination room is responsibility of the client.
- There are two forms of preparation for the installation of the Angix bases in the examination room, installed on floor, as of item 3.3.4.1 or in slab as of item 3.3.4.2.



- The arrangement and dimensions between conduits are available in the Sketch and drawing sheet (PNL00174) provided by XPRO.
- XPRO provides the drawing sheet (PNL00174 – Orientation of floor base anchoring, Angix) as illustrated in Figure 3.3.4-1.
- A wooden template must be manufactured using drawing sheet (PNL00174 – Orientation of floor base anchoring, Angix) as of Figure 3.3.4-1.
- The template must be manufactured for installation on floor as of item 3.3.4.1 or for installation in slab as of item 3.3.4.2.

Figure 3.3.4-1





3.3.4.1 Position of holes and cable boxes - Floor

- For the installation of the bases on the floor, it is necessary to manufacture a wooden template using drawing sheet (PNL00174 – Orientation of floor base anchoring, Angix) as of Figure 3.3.4.1-1. Pay attention to the opening for passing through cables.
- When installing the boxes for passing cables, conduits, and holes of anchors on the floor, use drawing sheet (PNL00174 – Orientation of floor base anchoring, Angix) as of Figure 3.3.4.1-1., in conjunction with the Sketch.

Figure 3.3.4.1-1

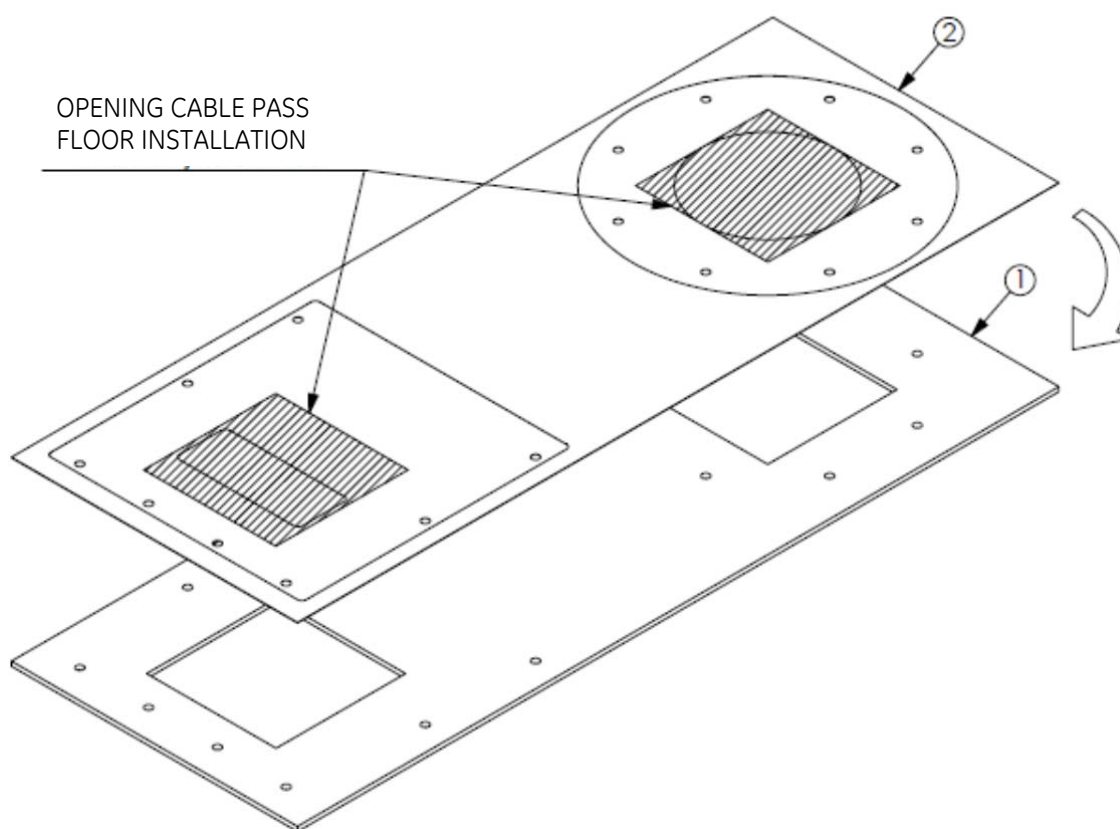


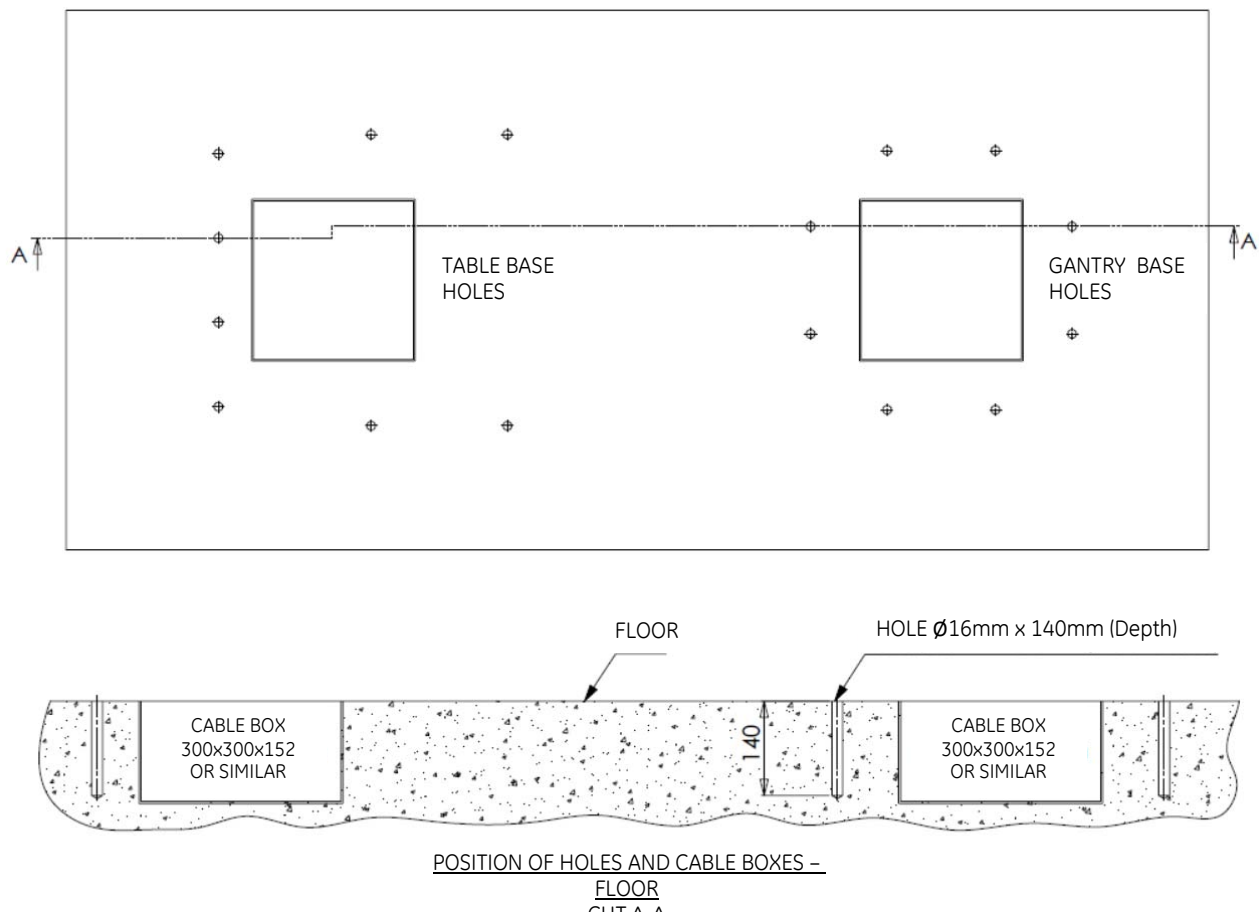
Table 3.3.4.1-1-Position of the holes and cable openings - Floor

N° ITEM	Code	Description
1	-	Wooden Template (Floor)
2	PNL00174	Orientation of Base Anchoring, Angix



- Place the wooden template manufactured as of drawing sheet (PNL00174) on the location indicated by the Sketch.
- With the proper tool, mark the locations indicated by the wooden template.
- Make 16 holes of 140 mm deep using a $\varnothing 16$ mm drill, as of Figure 3.3.4.1-2.
- For passing the cables on the floor, we recommend placing a cable box with 300x300x152mm or similar, as of figure 3.3.4.1-2.
- The floor must be prepared to receive the bases as illustrated by Figure 3.3.4.1-4.

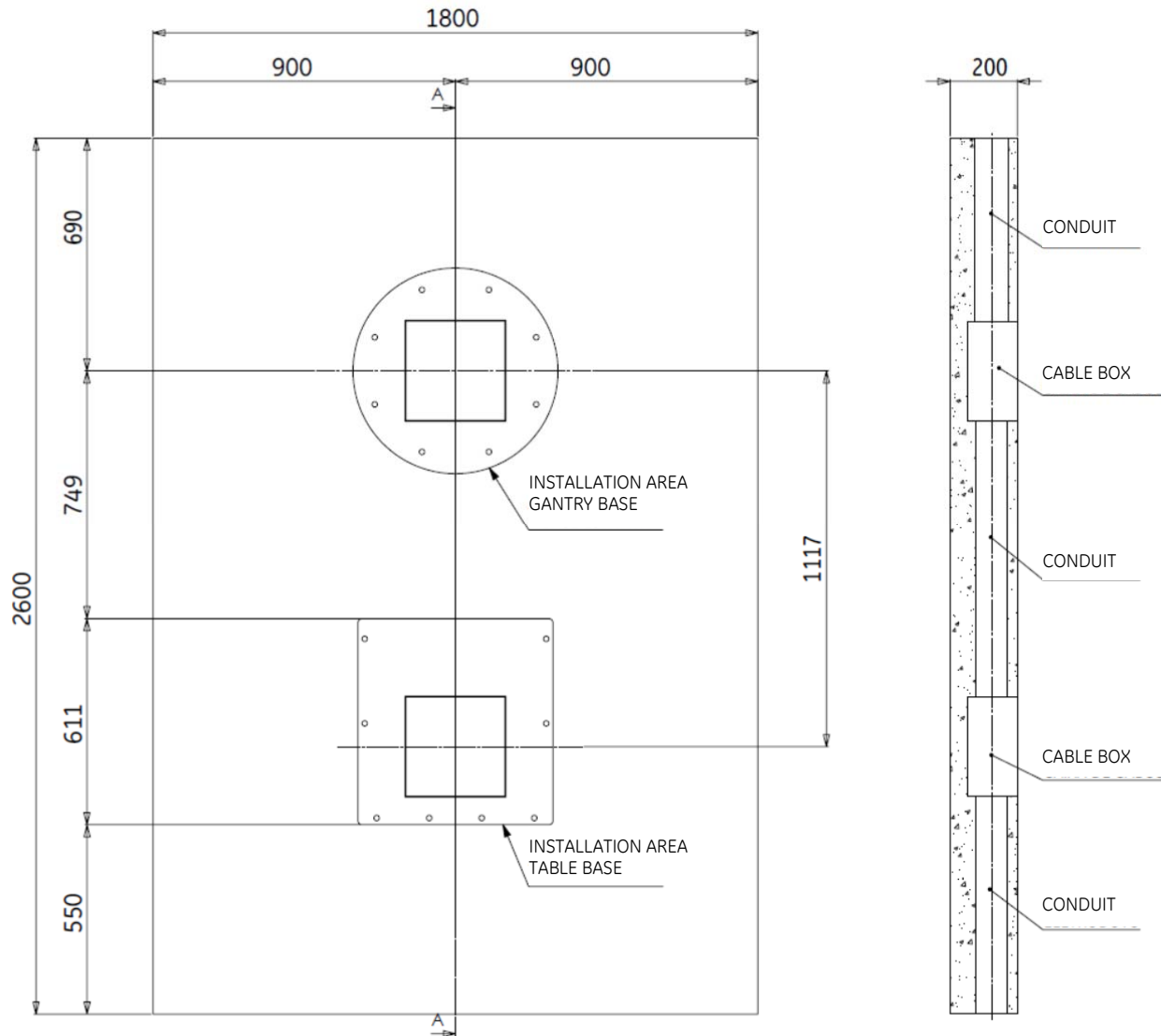
Figure 3.3.4.1-2





- For installing the Bases on floor, the minimum area of reinforced concrete shall be according to Figure 3.3.4.1-3, the concrete must have at least 20 cm of thickness.

Figure 3.3.4.1-3



Remark: Measures in millimeters.

Minimum area of reinforced concrete

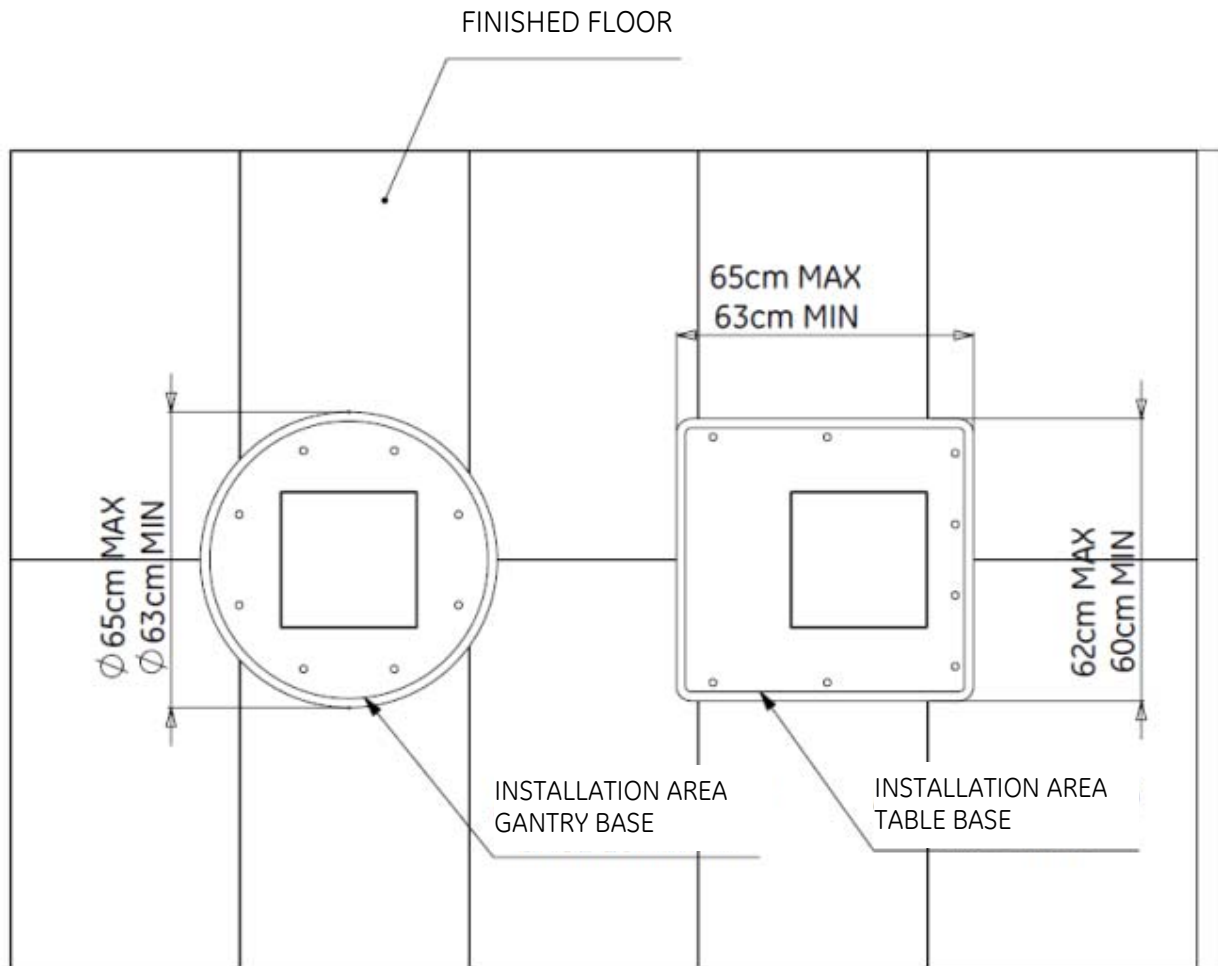


*In case of installation on floor, the minimum thickness of concrete is of 20 cm, with resistance of 50 Mpa of Traction.
 The non-compliance of these recommendations may cause serious damages to the equipment and injuries to users.*



- It is recommended to leave a space between the finished floor and the Bases, of 1 to 2 cm, as of Figure 3.3.4.1-4.

Figure 3.3.4.1-4



The preparation for the installation of the Angix bases in the examination room as of item 3.3.4.1 is responsibility of the client. XPRO will not be held responsible for problems caused by the incorrect execution of the procedure and/or by unauthorized professionals.



3.3.4.2 Position of holes and cable boxes - Slab

- For installing the bases on a slab, a wooden template must be manufactured using drawing sheet (PNL00174 – Orientation for base anchoring on soil, Angix) as of Figure 3.3.4.2-1, with attention to the opening for cable passing.
- When performing the installation of the cable boxes, the conduits and holes of anchors on the floor must use drawing sheet (PNL00174 – Orientation for base anchoring on soil, Angix) as of Figure 3.3.4.2-1, in conjunction with the Sketch.

Figure 3.3.4.2-1

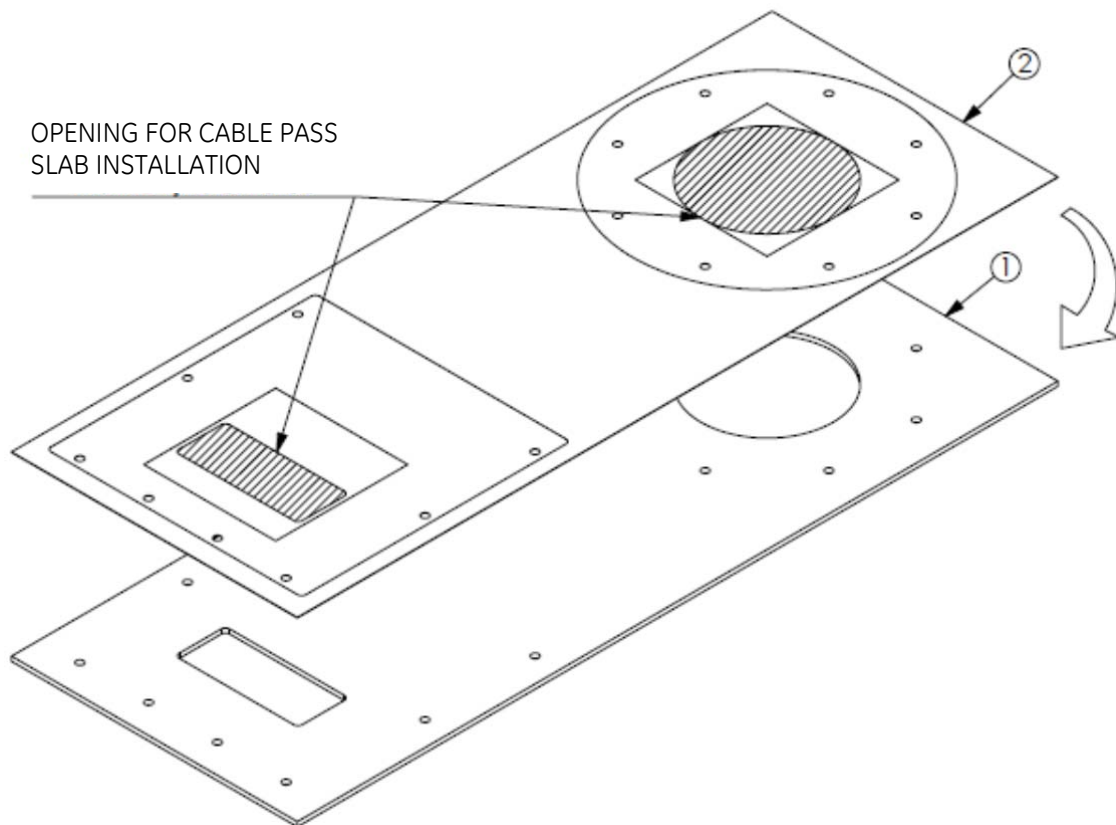


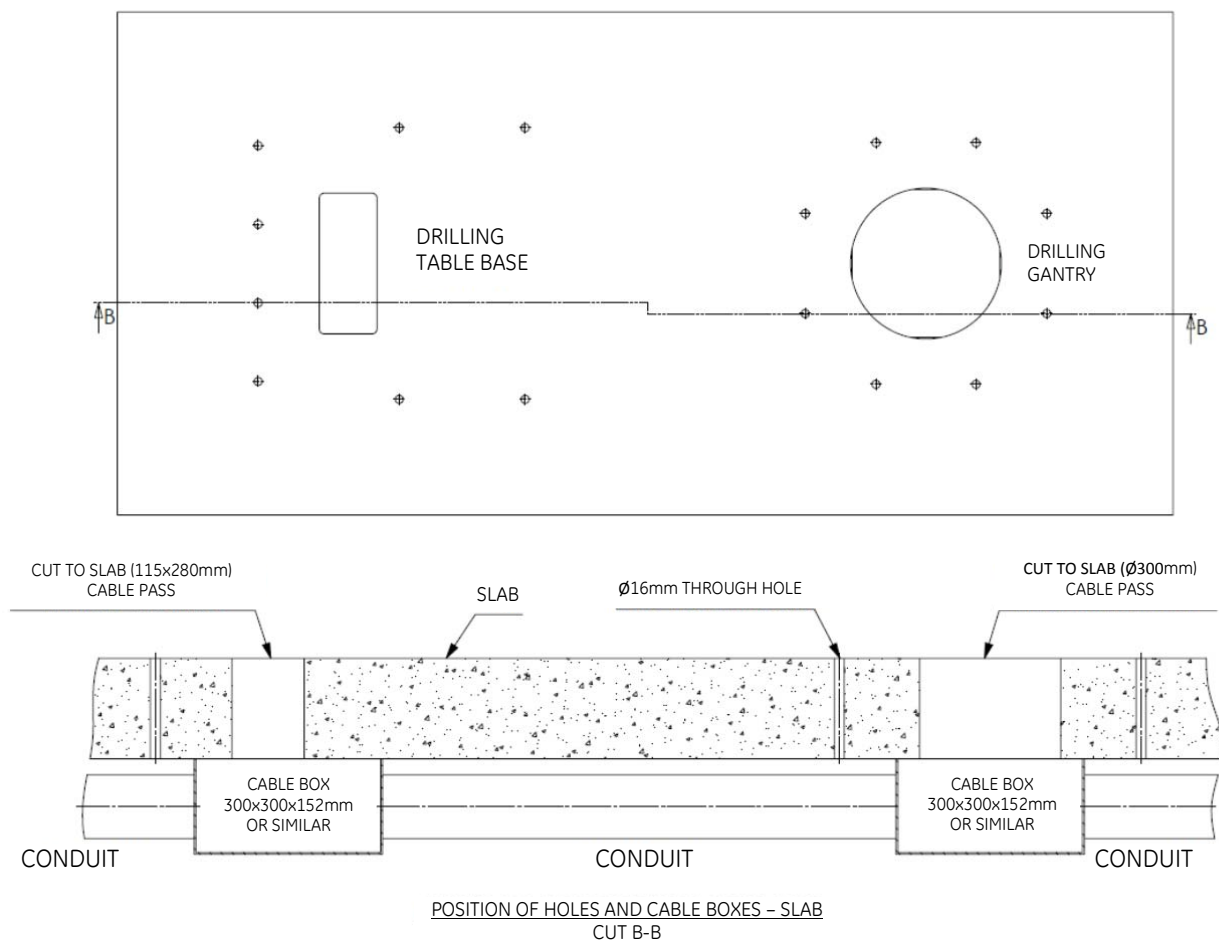
Table 3.3.4.2-1- Position of holes and cable boxes - Slab

ITEM	Code	Description
1	-	Wooden Template (Slab)
2	PNL00174	Orientation for Base Anchoring on Soil, Angix



- Place the wooden template manufactured as of drawing sheet (PNL00174) on the location indicated by the Sketch.
- With the appropriate tool make the marks on the locations indicated in the wooden template.
- Make 16 through holes using a $\varnothing 16$ mm drill, as of Figure 3.3.4.2-2.
- The cut must be made to the slab with $\varnothing 300$ mm in the position of the gantry base and with minimum dimension of 115 x 280 mm at the table base, as of Figure 3.3.4.2-2, using the template.
- The slab shall be prepared to receive the bases as illustrated by Figure 3.3.4.2-3.

Figure 3.3.4.2-2

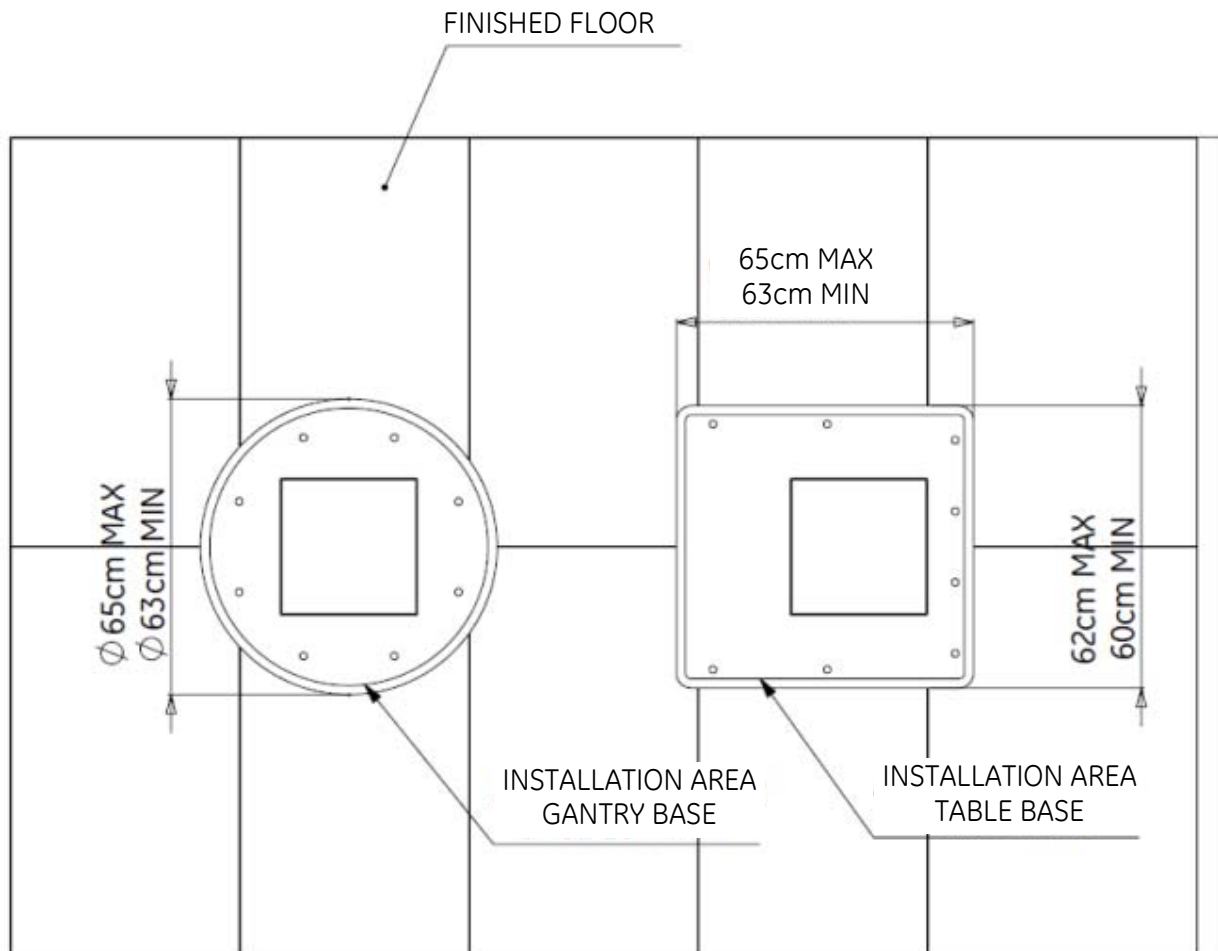


The cut to the slab for passing cables at the base of the table shall have minimum dimension of 115 x 280 mm, aligned with the table base.
The slab should not exceed 30 cm in thickness, and may be no obstruction between the cable boxes, one case does not meet the foregoing requirements the conduit should be installed in the slab.



- It is recommended to leave a space between the finished floor and the Bases, with 1 to 2 cm, as of Figure 3.3.4.1-3.

Figure 3.3.4.2-3



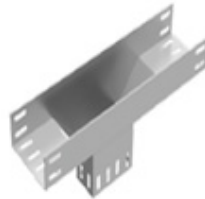
The preparation for installing the Angix bases in the examination room, as of item 3.3.4.2, is responsibility of the client. XPRO will not be held responsible for problems caused by the incorrect execution of the procedure and/or by unauthorized professionals.



3.3.5 Installation of the bases





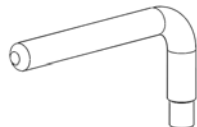
- The process of installation of the base is responsibility of XPRO.
- Material responsibility of the client: Adhesive Epoxy Resin (Sikadur 42) or similar and cable outtake box , according figure 3.3.5-1 or similar

Figure 3.3.55-1

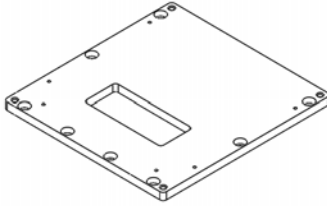
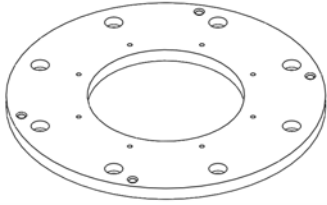



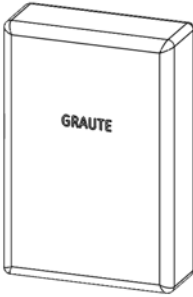


- For installing the bases, XPRO provides a kit with the items as of Table Table 3.3.5-1.

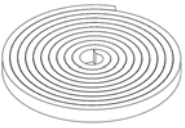

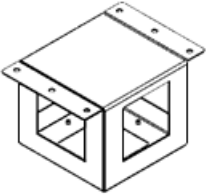
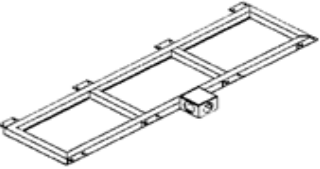
Table 3.3.5-1- Grout application mode – Floor or slab

ITEM	Code	Description	Qty.
	041157	12L Plastic Bucket.	2
	PMC04494	Wooden Pin.	16
	PMC04449	Slab support, Angix Soil Base.	16
	040700	Zinc 5 Hex Nut - 1/2".	48
	PMC04448	Handle for moving Floor Anchoring Bases, Angix.	4



ITEM	Code	Description	Qty.
	PMC04124	Table Anchoring Base, Angix	1
	PMC04125	Arc suite anchoring base, Angix	1
	040702	Zinc flat washer 1/2" - 1 1/4" Ext.	32
	-	Threaded Rod Ø1/2" x 13FPP x 500mm long ASTM A 193 GR. B7.	16
	002700	Insulation sealing – Silicone.	1
	041144	Grout, 25Kg pack.	1



ITEM	Code	Description	Qty.
	PMC04588	Rectangular Profile, 20x20mm, Adhesive Sponge Rubber – 2.5M.	2
	041142	Lithium nautical white grease (SACHET).	1
	22799	PMC00609_04 – Cable intake box, arc, ceiling	1
	24281	PMC02739_01_A – Automated monitor support base	1



- For handling the bases, assembly the handles as of Figure 3.3.5-1 and Figure 3.3.5-2.

Figure 3.3.5-1

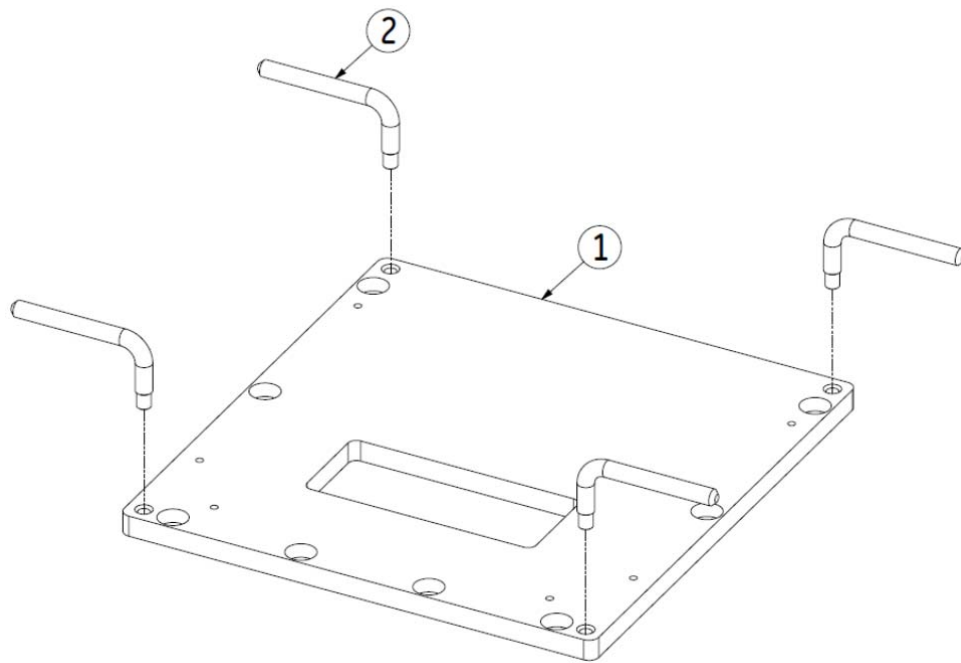


Table 3.3.5-2- Grout application mode - Floor or slab

ITEM No.	Code	Description
1	-	Angix Table anchoring Base
2	-	Angix Floor Anchoring Base moving handle



Figure 3.3.5-2

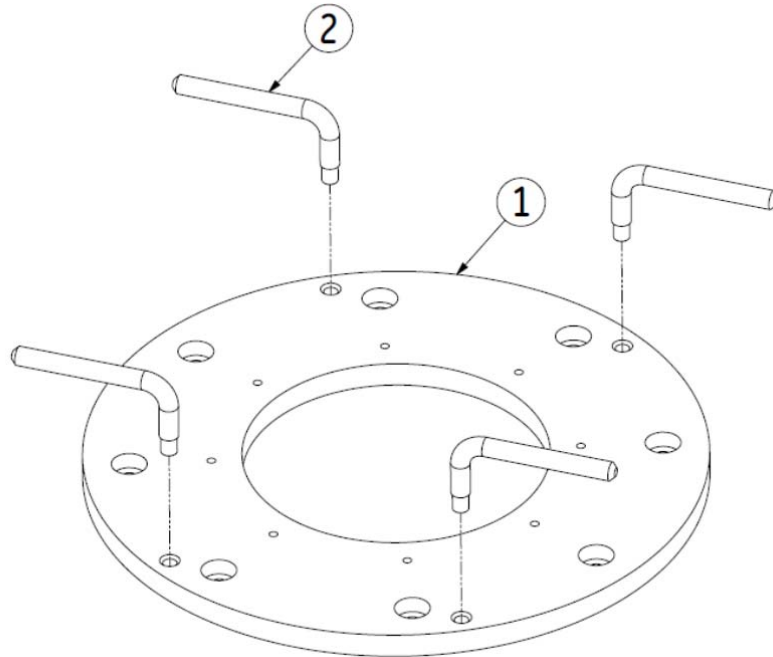


Table 3.3.5-3- Grout application mode - Floor or slab

ITEM No.	Code	Description
1	-	Angix Arc Set anchoring Base
2	-	Angix Floor Anchoring Base moving handle



- For grouting, first place the handles in the location as of Figure 3.3.5-3.

Figure 3.3.5-3

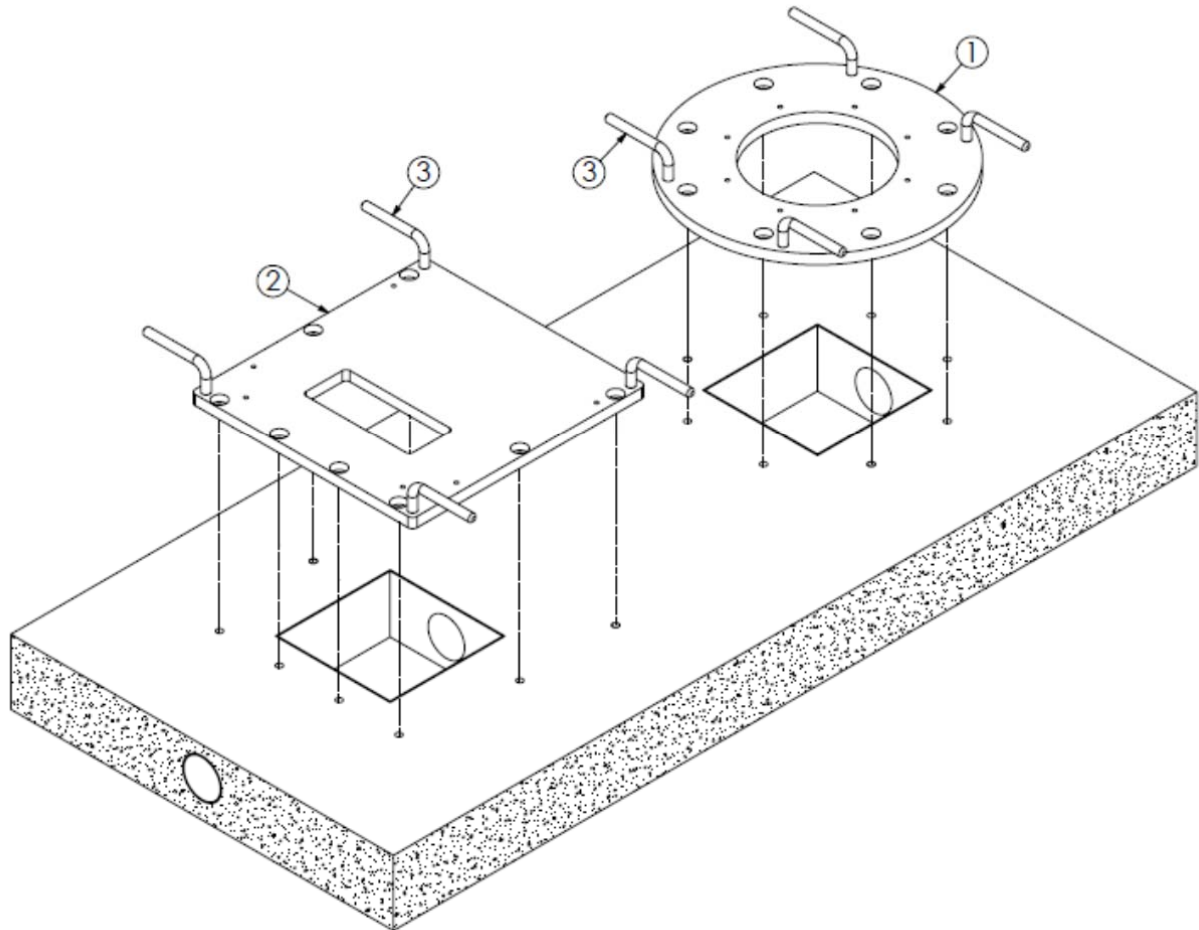


Table 3.3.5-4- Grout application mode - Floor or slab

ITEM No.	Code	Description
1	-	Angix Arc Set anchoring Base
2	-	Angix Table anchoring Base
3	-	Angix Floor Anchoring Base moving handle



- Assemble 4 anchors (or bolts) in each base, as of Figure 3.3.5-4.

Figure 3.3.5-4

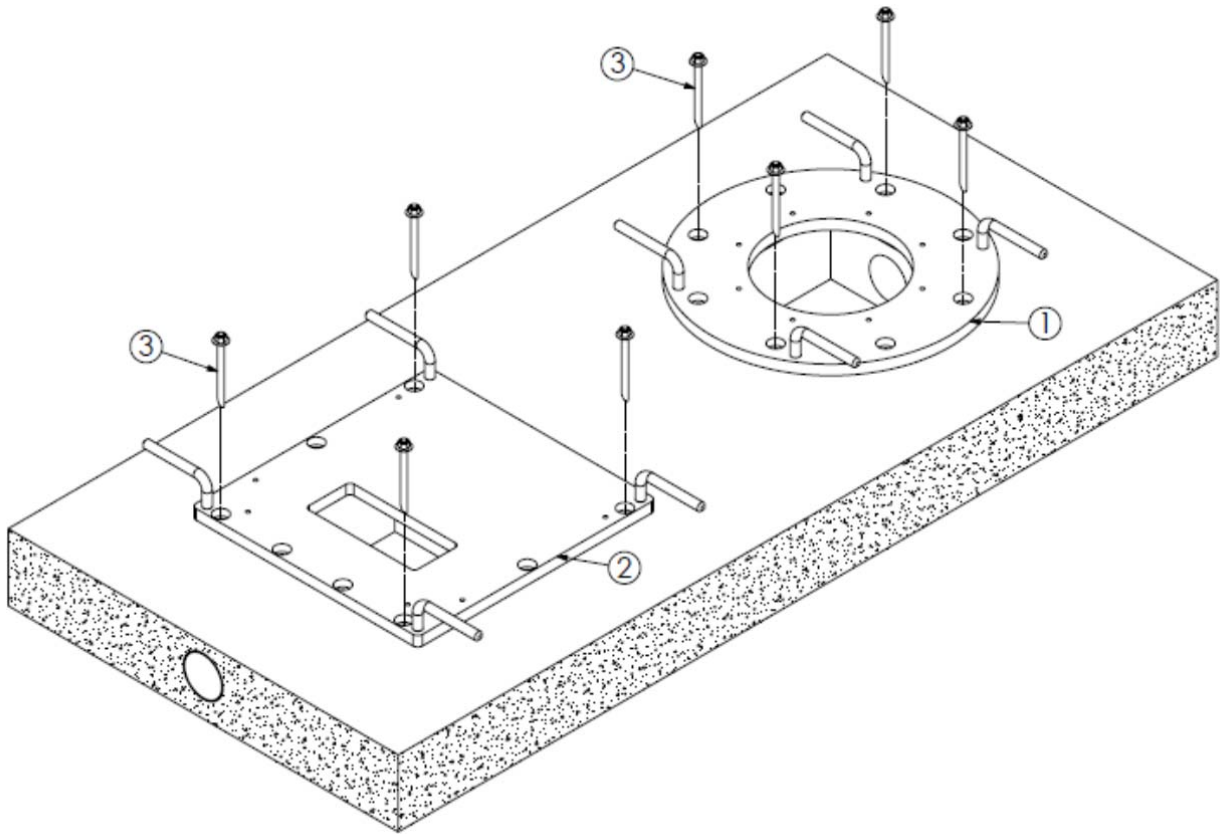


Table 3.3.5-5- Grout application mode - Floor or slab

ITEM No.	Code	Description
1	-	Angix Arc Set anchoring Base w/ Handle
2	-	Angix Table anchoring Base w/ Handle
3	-	Anchor (or Bolt)



- Before attaching the rubber profile to the floor, clean the contact region with a humid cloth.
- Place the sponge rubber profile around the bases, and use silicone to seam the profiles, as of Figure 3.3.5-5.

Figure 3.3.5-5

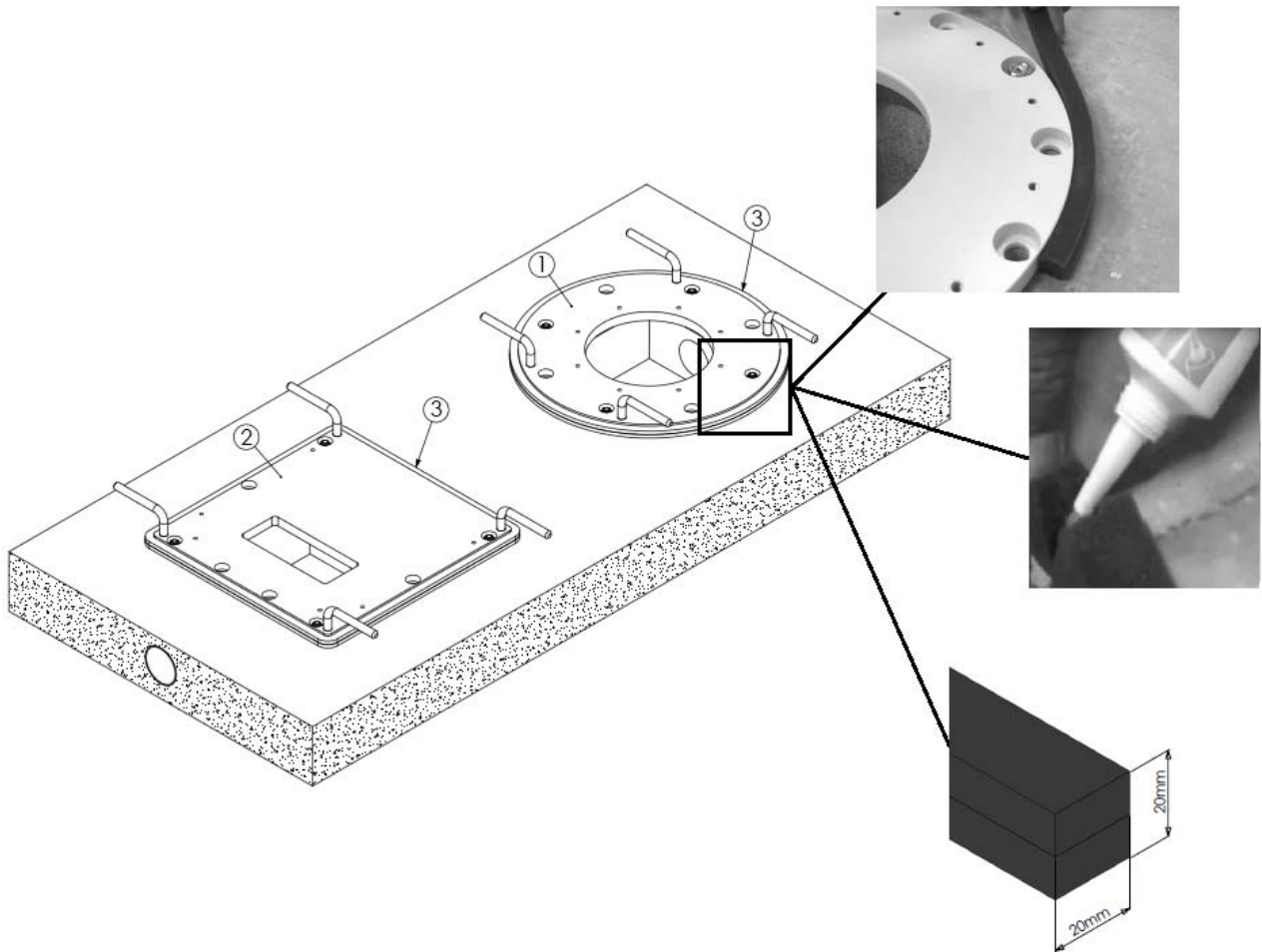


Table 3.3.5-6-Grout application mode - Floor or slab

ITEM No.	Code	Description
1	-	Angix Arc Set anchoring Base w/ Handle
2	-	Angix Table anchoring Base w/ Handle
3	-	Sponge rubber Profile Strip – 2.5M



- After concluding the sealing with the rubber profile, the bases with the anchors (or bolts) may be removed as of Figure 3.3.5-6.

Figure 3.3.5-6

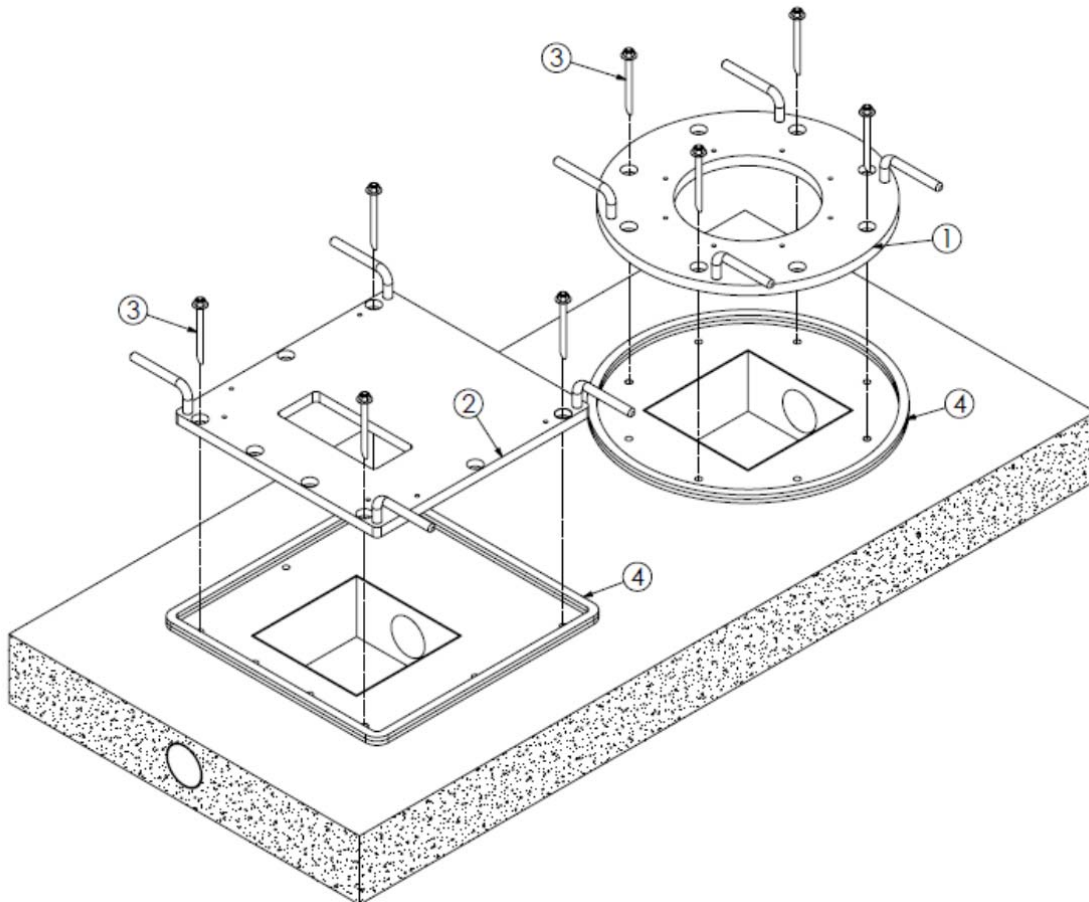


Table 3.3.5-7-Grout application mode - Floor or slab

ITEM No.	Code	Description
1	-	Angix Arc Set anchoring Base w/ Handle
2	-	Angix Table anchoring Base w/ Handle
3	-	Anchor (or Bolt)
4	-	Sponge rubber Profile Strip – 2,5M



- Before assembling the pins, apply grease to the region of contact with the grout.
- Assemble the wooden pins into the holes, ensuring sealing as of Figure 3.3.5-7.

Figure 3.3.5-7

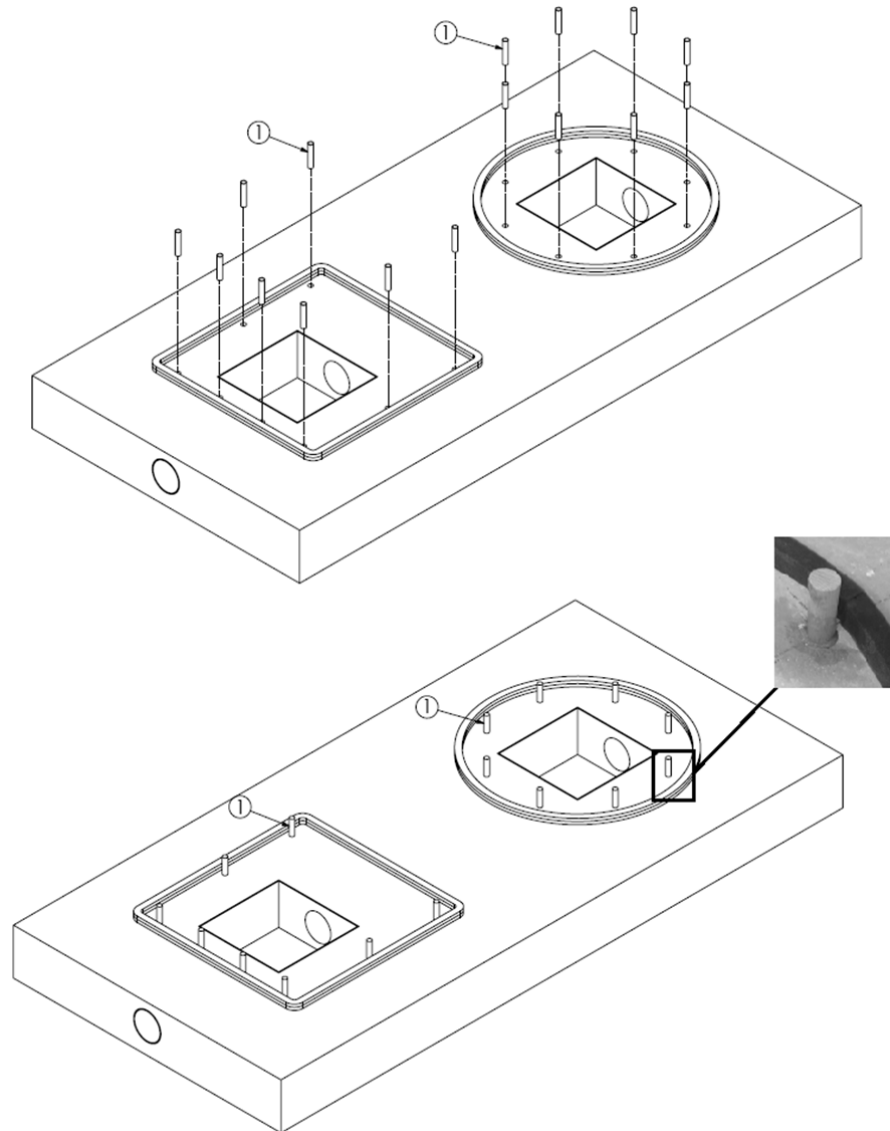


Table 3.3.5-8- Grout application mode - Floor or slab

ITEM No.	Code	Description
1	-	Wooden Pin



- Provide an internal tray around the cable boxes using cardboard parts (may be a package box), as of Figure 3.3.5-8.
- All cracks and holes must be sealed with silicone as of Figure 3.3.5-8.

Figure 3.3.5-8

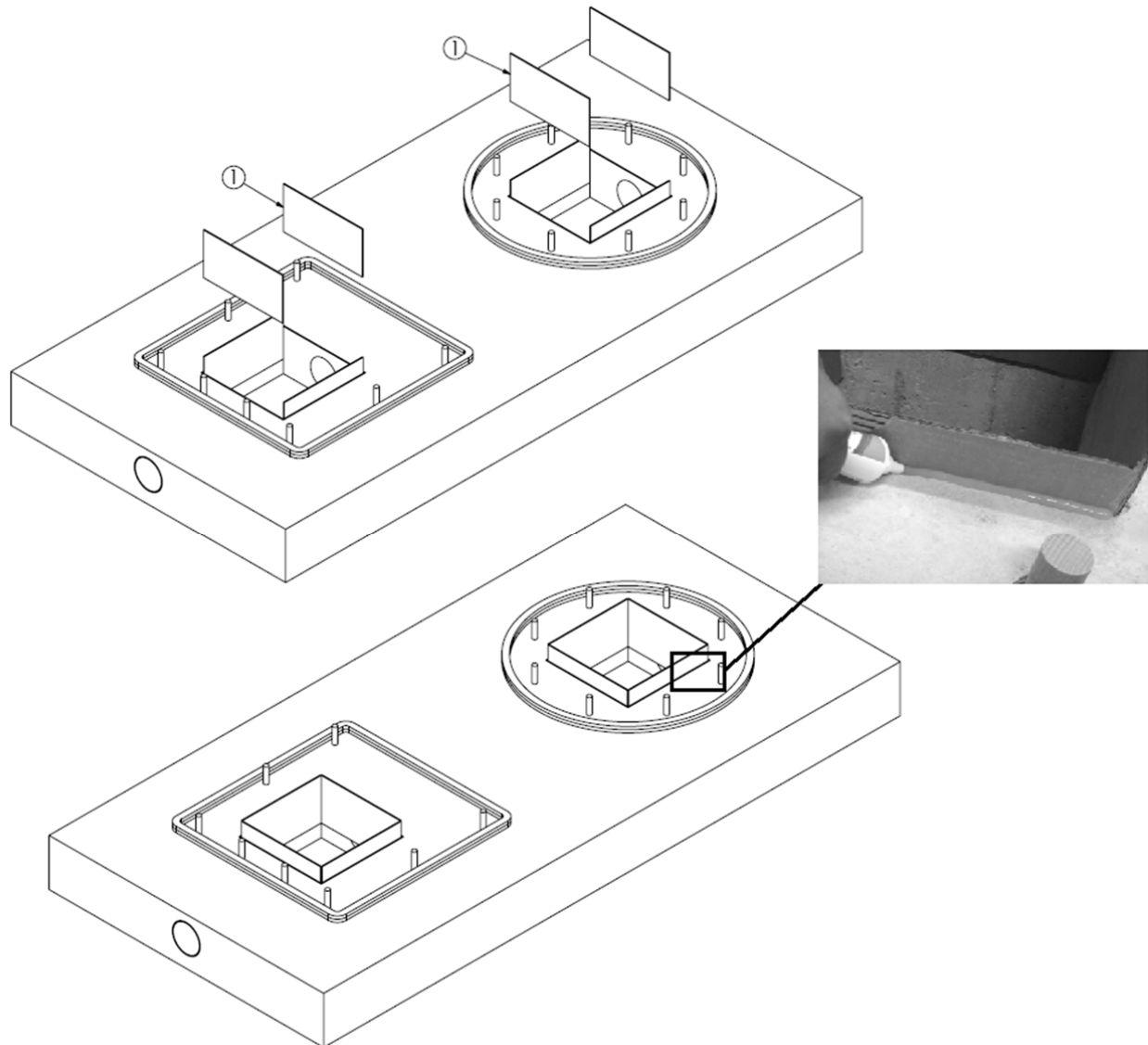


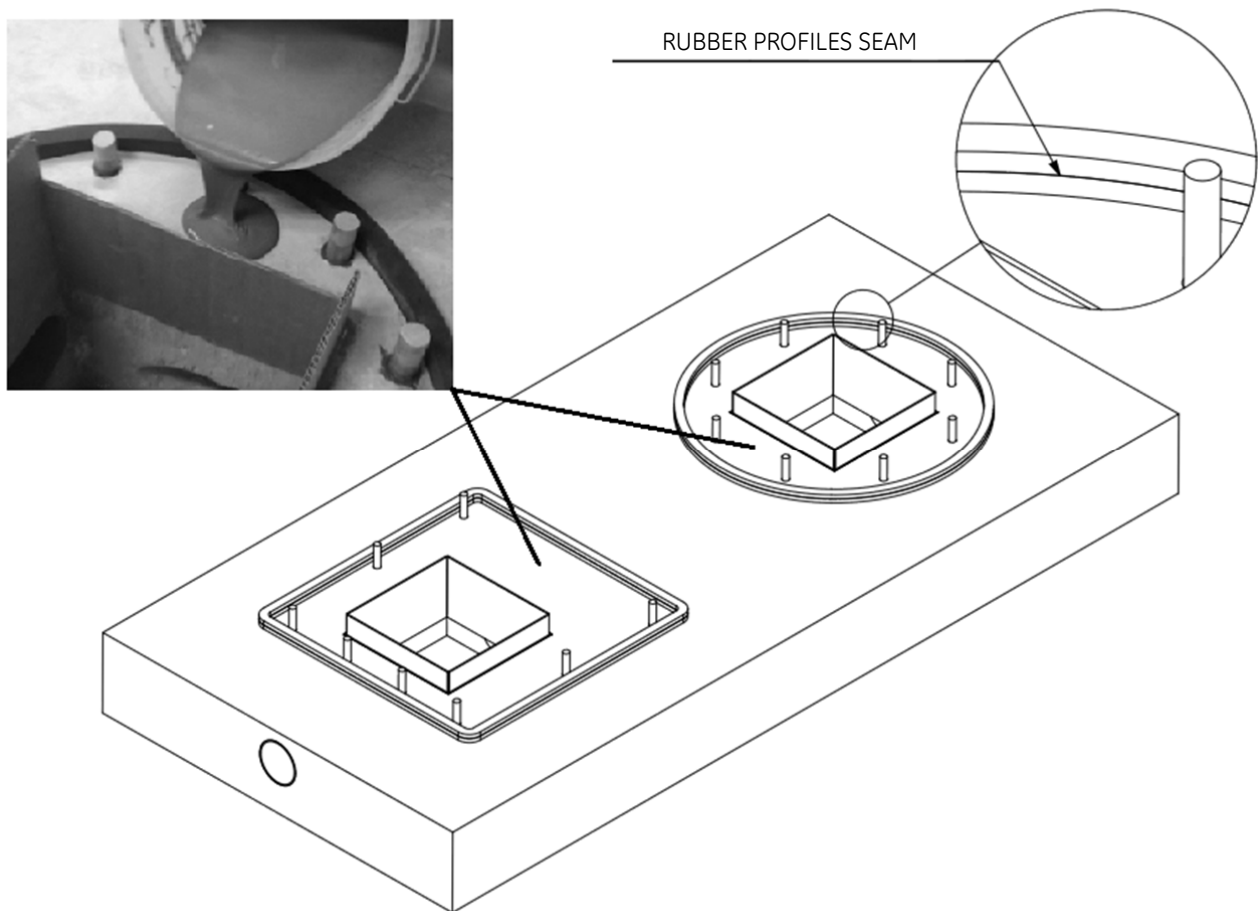
Table 3.3.5-9-Grout application mode - Floor or slab

ITEM No.	Code	Description
1	-	Cardboard Part



- Prepare the grout (according to the specification), as most liquid as possible.
- Wash the location before grouting.
- Pour the grout into the location of installation of the bases as of Figure 3.3.5-9.
- The grout must have thickness between 6 and 10mm, and may use the seam of the rubber profiles as a reference for applying the grout as of Figure 3.3.5-9.

Figure 3.3.5-9



After grouting, wait approximately 4 hours to remove the sealing materials, and 24 hours for applying the anchors.

- Carefully remove the sealing materials as of Figure 3.3.5-10.



Figure 3.3.5-10

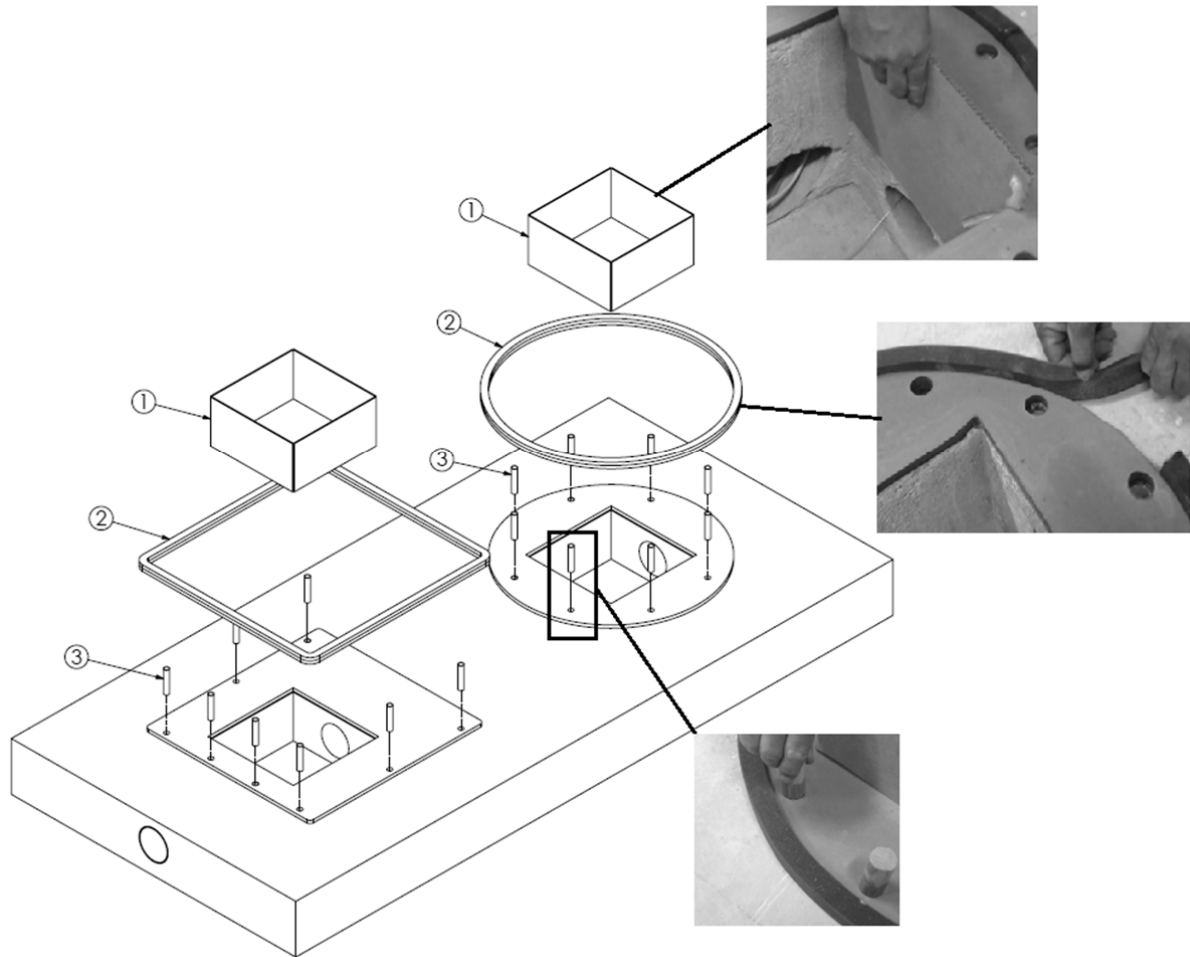


Table 3.3.5-10-Grout application mode - Floor or slab

ITEM No.	Code	Description
1	-	Cardboard Part
2	-	Sponge rubber Profile Strip – 2,5M
3	-	Wooden Pin



3.3.6 Installing the bases with anchors

- The installation of the anchors may be provided in two ways: floor installation, as of item 3.3.7, or slab installation, as of 3.3.7-1.

3.3.7 Installing the bases on floor with anchors

- Cut 16 Threaded rods 1/2" x 13FPP x 500mm with length of 160mm as of Figure 3.3.7-1.

Figure 3.3.7-1

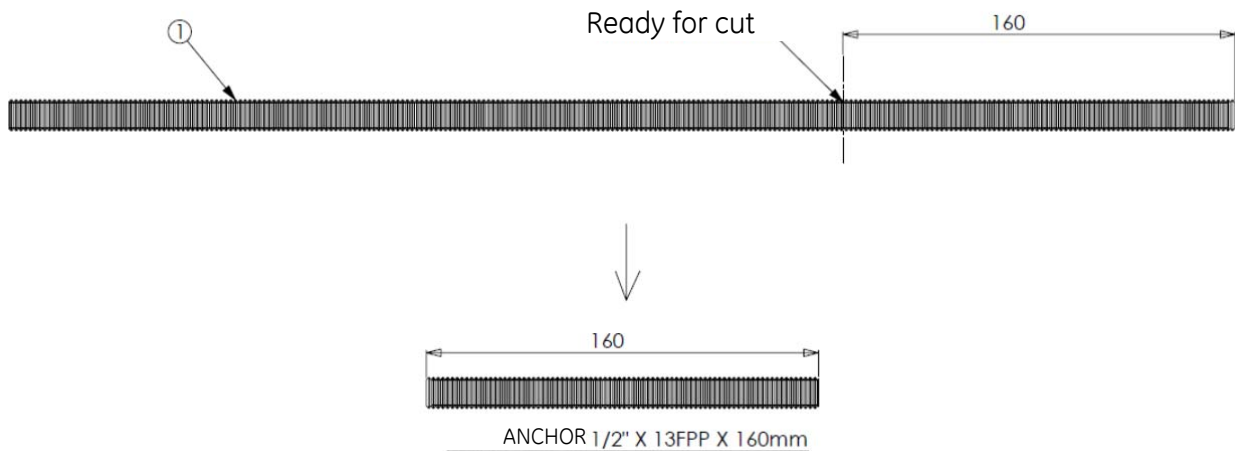


Table 3.3.7-1-Installing the floor bases with anchors

ITEM No.	Code	Description
1	-	Threaded Rod Ø1/2" x 13FPP x 500mm length / ASTM A 193 GR. B7



- Use the Ø16mm drill into the holes, ensuring a depth of 140 mm.
- Clean all holes.
- Install the Bases at the location as of Figure 3.3.7-2.

Figure 3.3.7-2

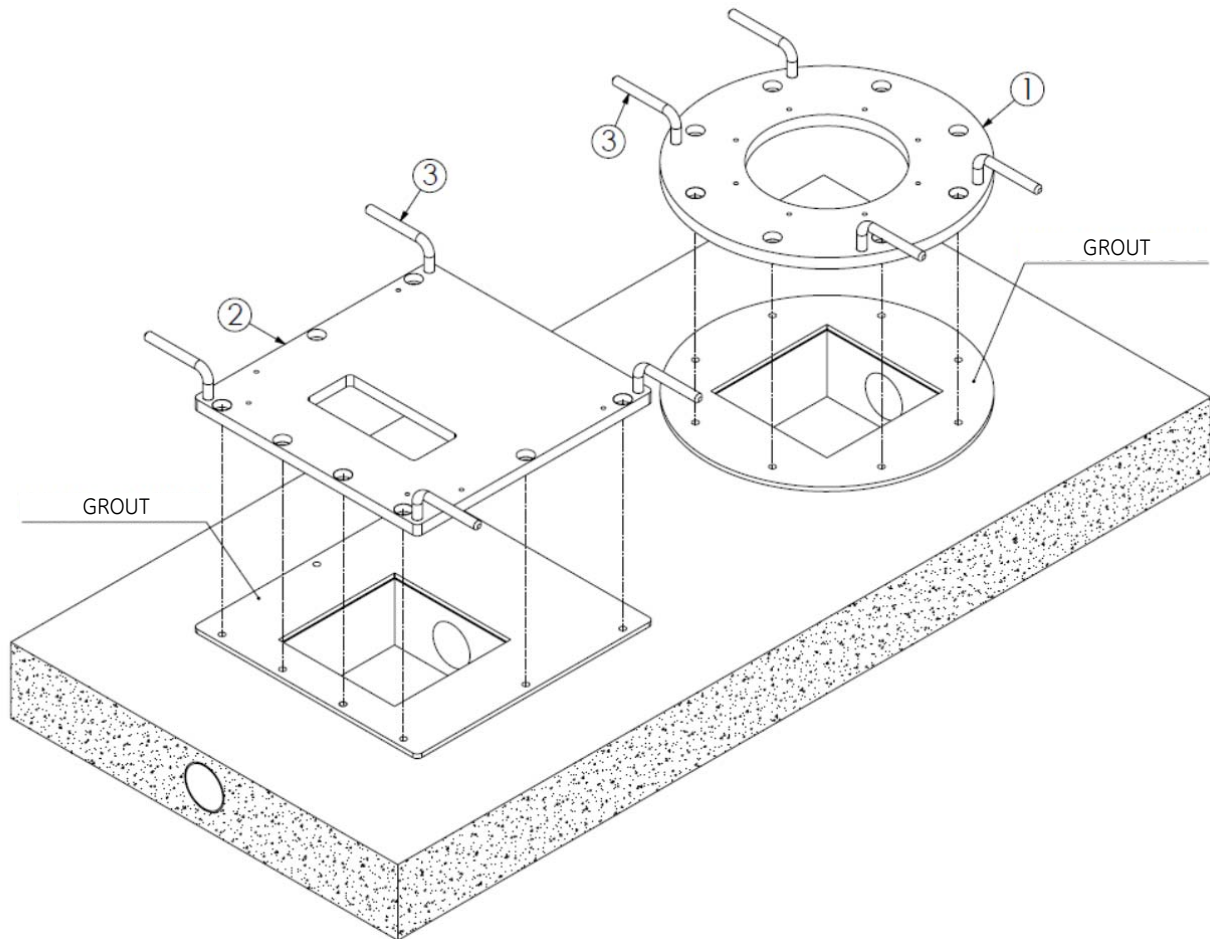


Table 3.3.7-2 - Installing the floor bases with anchors

ITEM No.	Code	Description
1	-	Angix Table anchoring Base
2	-	Angix Arc Set anchoring Base
3	-	Angix Floor Anchoring Base moving handle



- Place the nut approximately 2 mm (or 1 thread wire) above the end of the threaded rod, as indicated in Figure 3.3.7-3.

Figure 3.3.7-3





- Assemble 4 anchors in each base as of Figure 3.3.7-4.

Figure 3.3.7-4

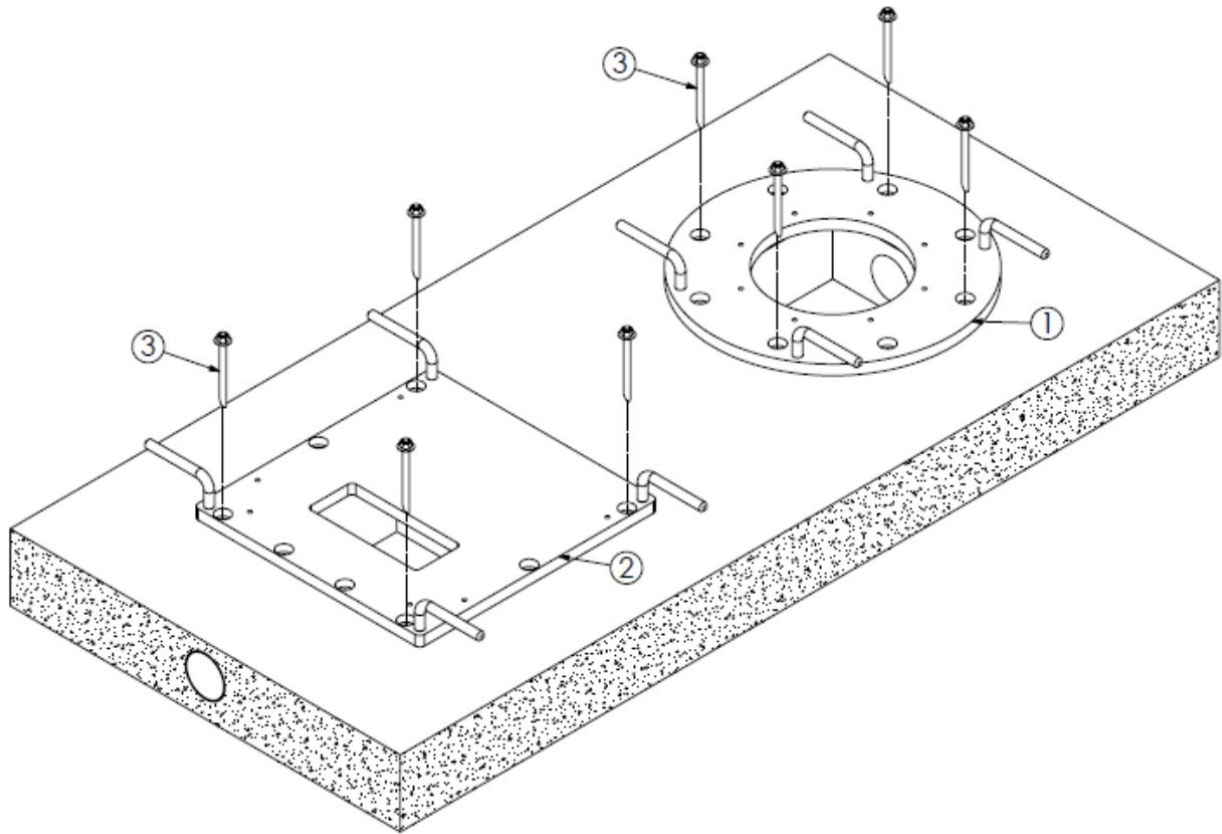


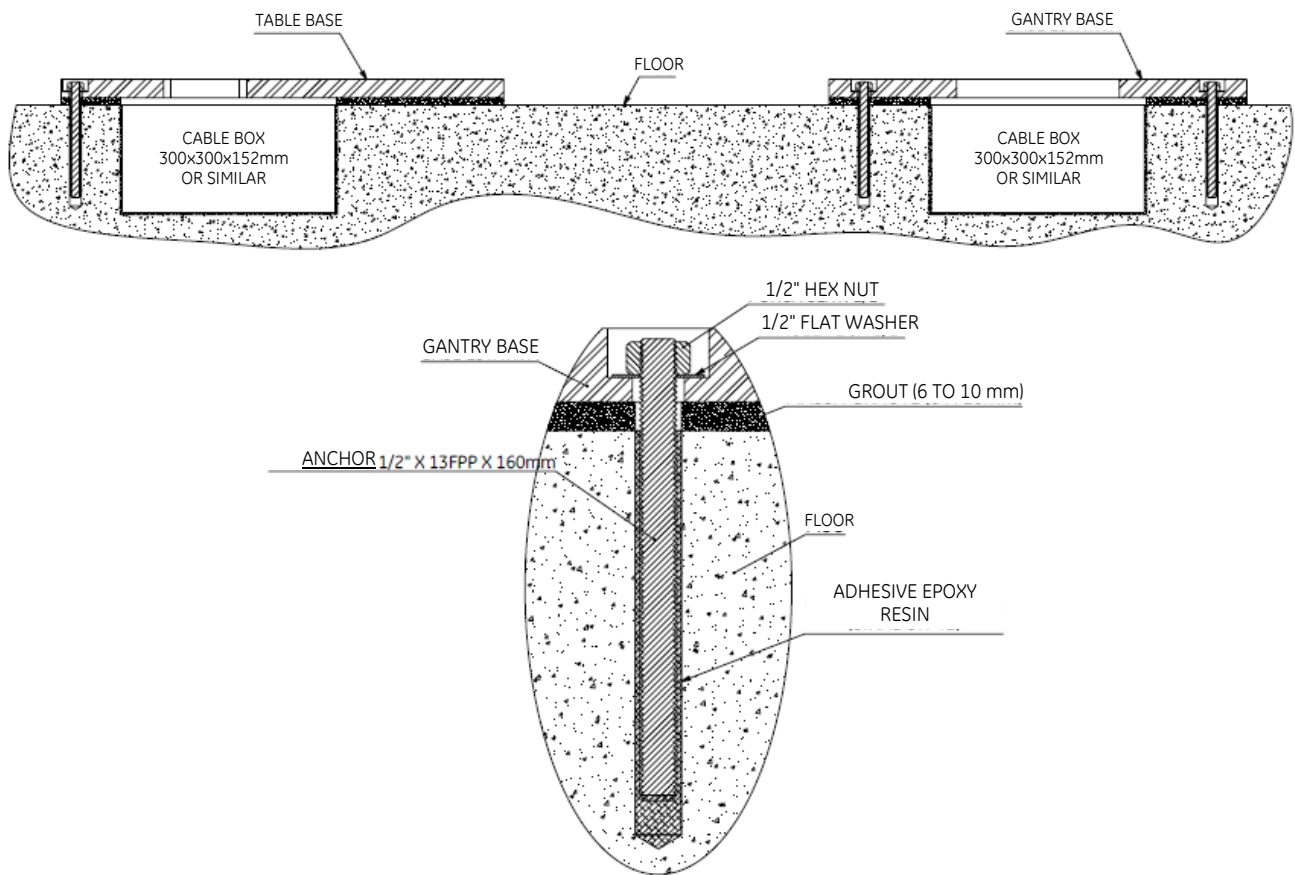
Table 3.3.7-3- Installing the floor bases with anchors

ITEM No.	Code	Description
1	-	Angix Arc Set anchoring Base w/ Handle
2	-	Angix Table anchoring Base w/ Handle
3	-	Anchor



- For securing the anchors, use Adhesive Epoxy Resin (Sikadur 42) or similar, with such acquisition being responsibility of the client.
- Prepare the Adhesive Epoxy Resin (as specified by the manufacturer).
- Right after pouring the Adhesive Epoxy Resin into the holes, insert the assembled anchors with flat washer and nut, according to the example of figure 3.3.7-5.

Figure 3.3.7-5



XPRO does not provide the Adhesive Epoxy Resin (Sikadur 42) or similar, with the acquisition being responsibility of the client.



All nuts must be fastened with torque of 80 N.m, after 24 hours drying the adhesive epoxy resin.



3.3.8 Installing the bases in slab

- Place the Bases on the respective locations, and then assemble the threaded rods as of Figure 3.3.8-1.

Figure 3.3.8-1

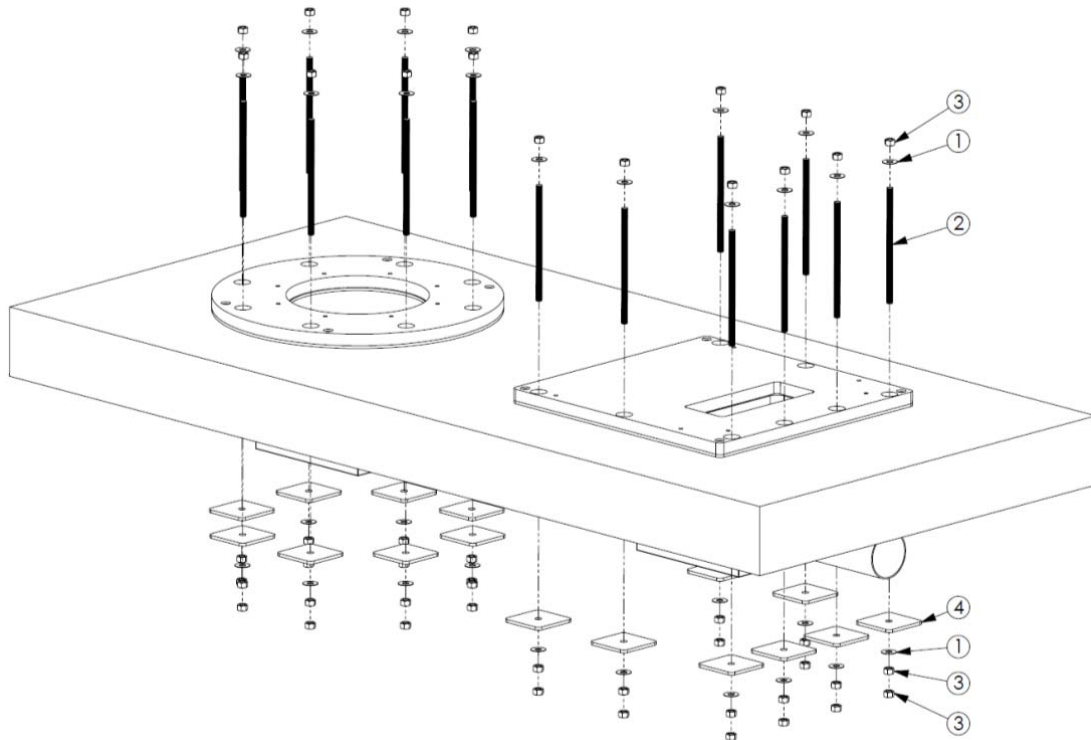


Table 3.3.8-1- Installing the bases in slab with bolts

ITEM No.	Code	Description
1	-	1/2" Zinc Flat Washer - 1 1/4" external
2	-	Threaded rod Ø1/2" x 13FPP x 500mm Length / ASTM A 193 GR. B7
3	-	Level 5 Zinc Hex Nut 5 - 1/2"
4	-	Angix Floor Base slab support



All nuts must be fastened with torque of 80 N.m, and cut off the excess of threaded rods.



- To install the Angix Bases in slab, follow the example illustrated in Figure 3.3.8-2.

Figure 3.3.8-2

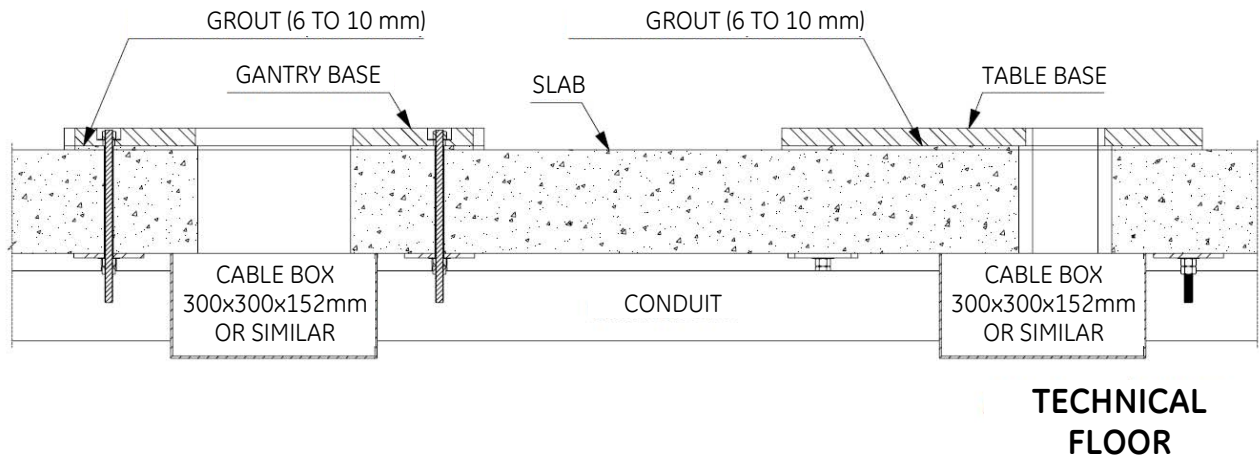


Figure 0-3

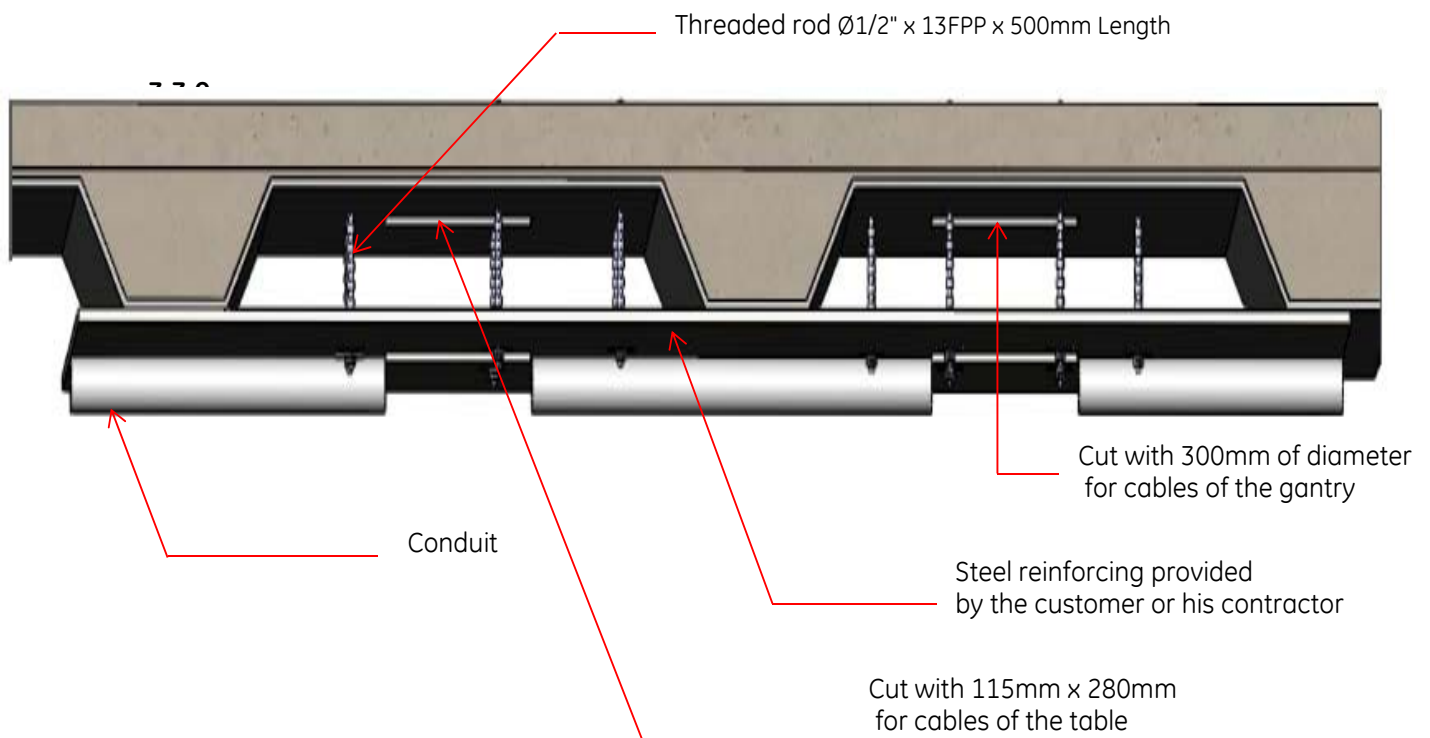


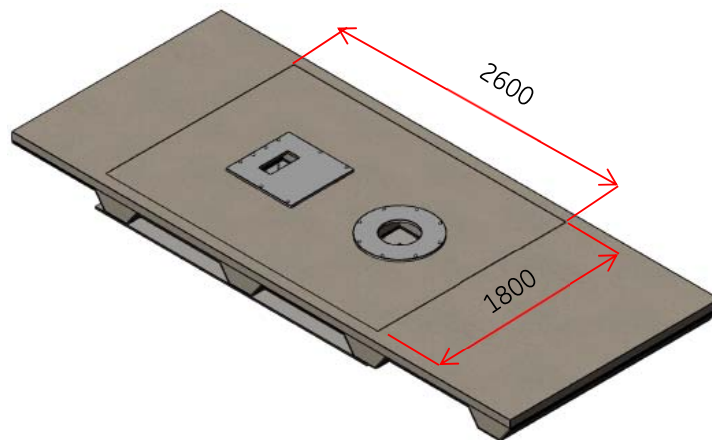


Table 3.3.8-3- Installing the bases in metal deck with bolts

ITEM No.	Code	Description
1	-	1/2" Zinc Flat Washer - 1 1/4" external
2	-	Threaded rod Ø1/2" x 13FPP x 500mm Length / ASTM A 193 GR. B7
3	-	Level 5 Zinc Hex Nut 5 - 1/2"
4	-	Angix Floor Base slab support

- In the metal deck installation, verify the reinforced area, according Figure 3.3.8-4.

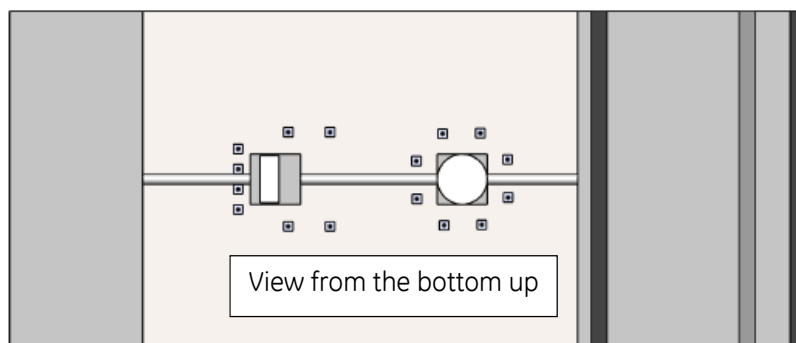
Figure 3.3.8-4



Values in mm

- Place the Bases on the respective locations, and then assemble the threaded rods as of Figure 3.3.8-5. All nuts be fastened with torque of 80 N.m, and cut off the excess of threaded rods.

Fiaure 3.3.8-5



3.3.9



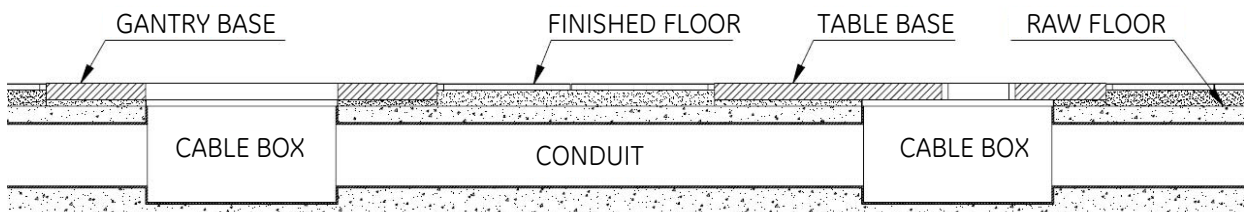
The preparation for the installation of the Angix bases in the examination room as of item 3.3.4.1 is responsibility of the client. XPRO will not be held responsible for problems caused by the incorrect execution of the procedure and/or by unauthorized professionals.



3.3.9 Leveling with finished floor

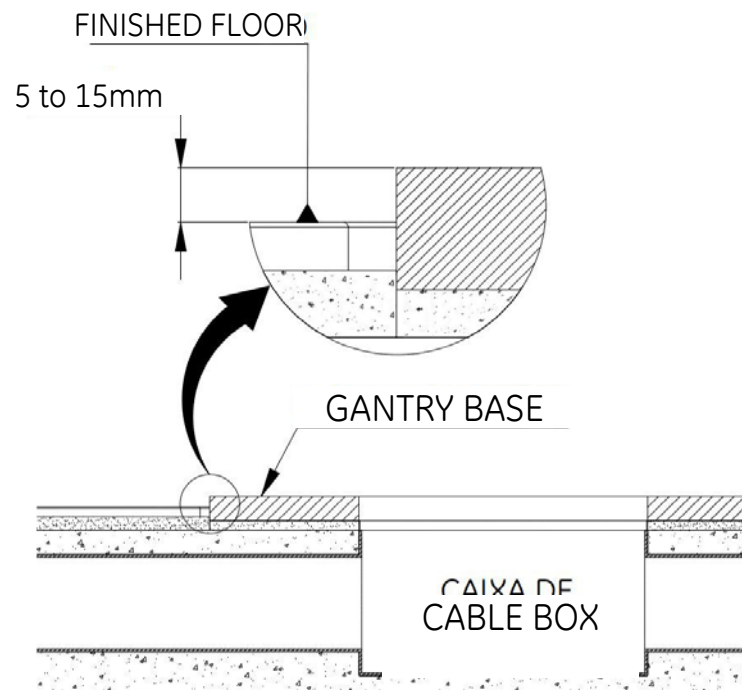
- The finished floor must be leveled with the Bases of installation of the Table and Gantry as of Figure 3.3.9-1.

Figure 3.3.9-1



- The bases shall be above the finished floor, with a height of 5 to 15mm from the floor, as indicated in Figure 3.3.9-2.

Figure 3.3.9-2



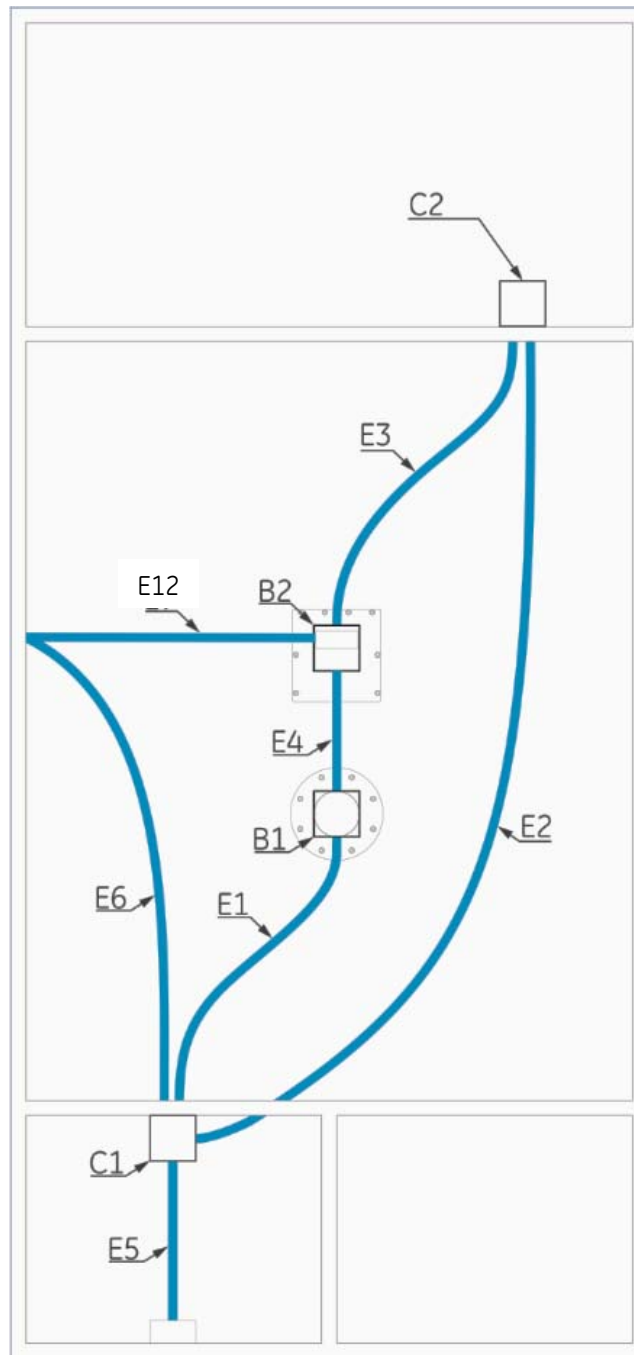
The bases shall be above the finished floor, with height of 5 to 15mm from the floor.



3.3.10 Arrangement of Floor conduits

- It is necessary to install conduits, as set forth by Figure 3.3.10-1.
- The dimensions will be informed in the sketch.

Figure 3.3.10-1

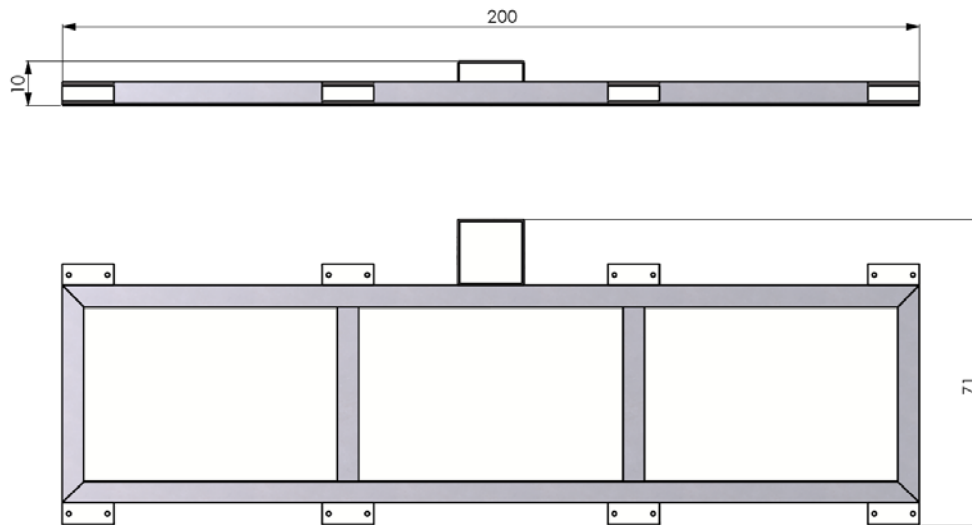




3.3.11 Base of attachment of monitor support and ceiling boxes

- The base of the monitor support as of Figure 3.3.11-1 must be attached to the ceiling as not to allow horizontal or vertical movement. It is suggested to weld wings at the edges of the frame, secured by bolt, or, if the ceiling height is too high and requires the installation of the frame away from the slab, the provision of crossed beams for the attachment is suggested.
- The cable intake box of arc as of Figure 3.3.11-2 and the cable outtake box of the Póllux X-ray Generator Póllux as of Figure 3.3.11-3 shall also be attached to the ceiling, leveled with the lower face of the monitor support base, as of Figure 3.3.11-1.

Figure 3.3.11-1



Note: Measures in centimeters.

Figure 3.3.11-2

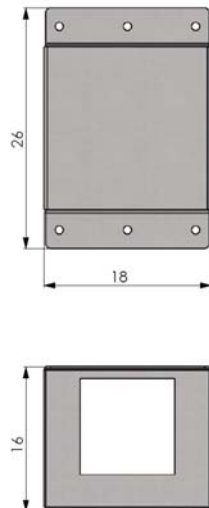
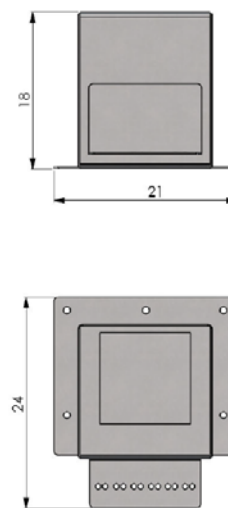


Figure 3.3.11-3

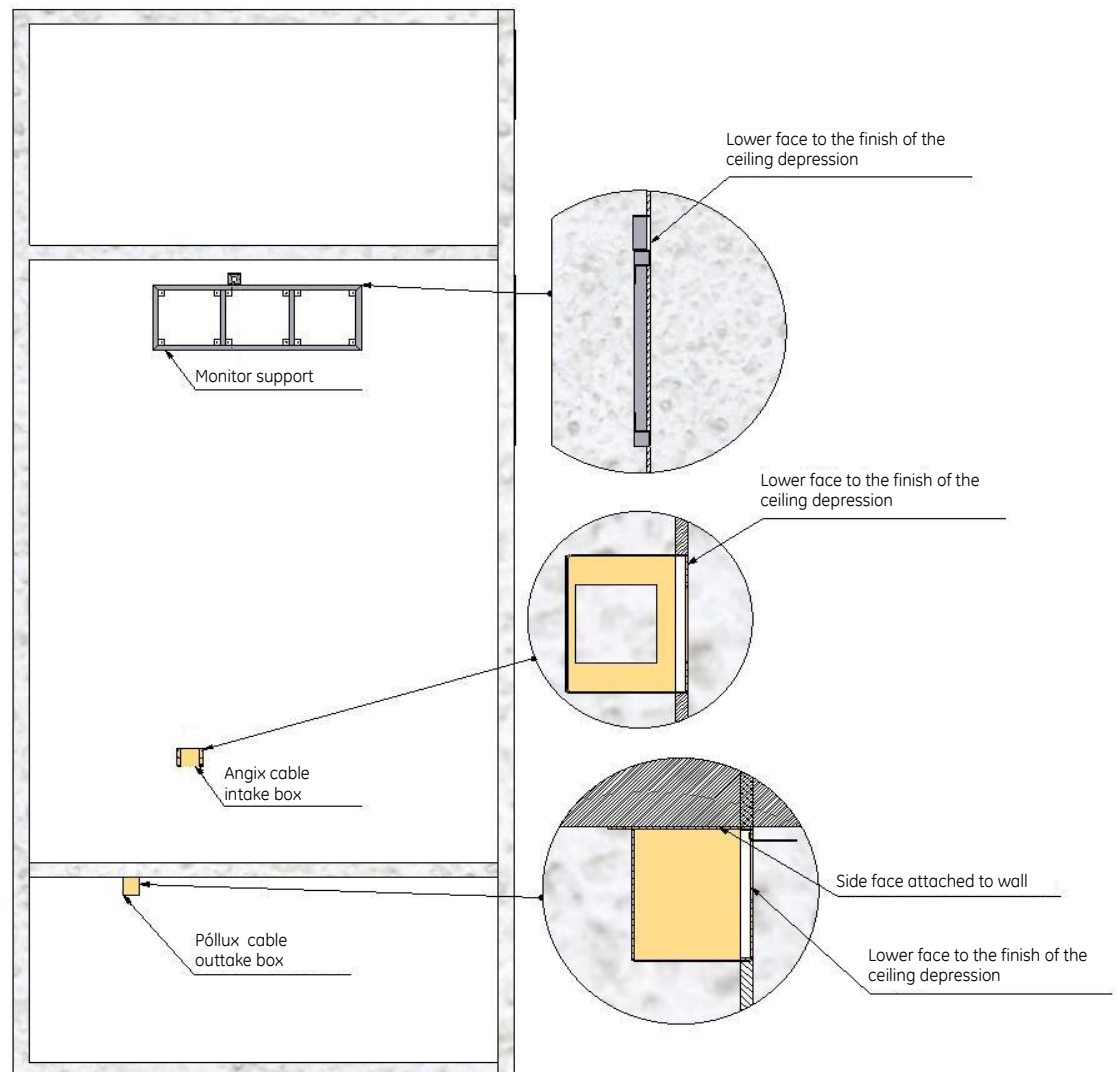




3.3.12 Attaching the monitor support base to the ceiling

- Figure 3.3.12-1 shows the position of the monitor support base and the cable outtake boxes of Póllux and Arc C.
- The monitor support base may be secured by means of wings as of Figure 3.3.12-2.

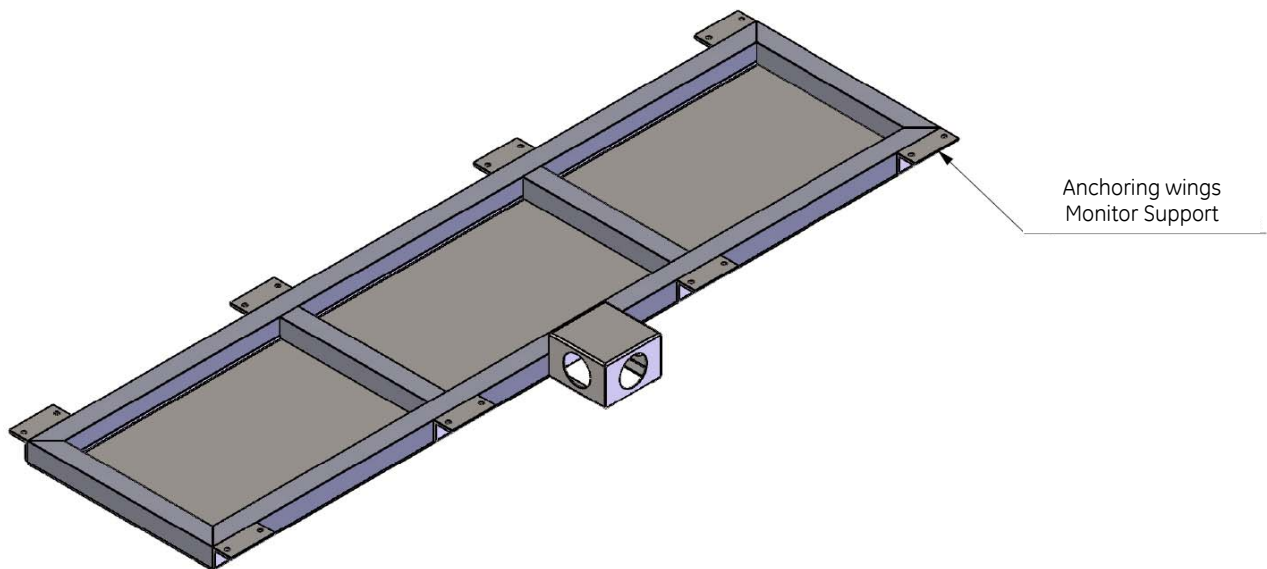
Figure 3.3.12-1



- In case the ceiling height exceeds the limits determined by this manual, the installation of a structure to attach the base is suggested.



Figure 3.3.12-2

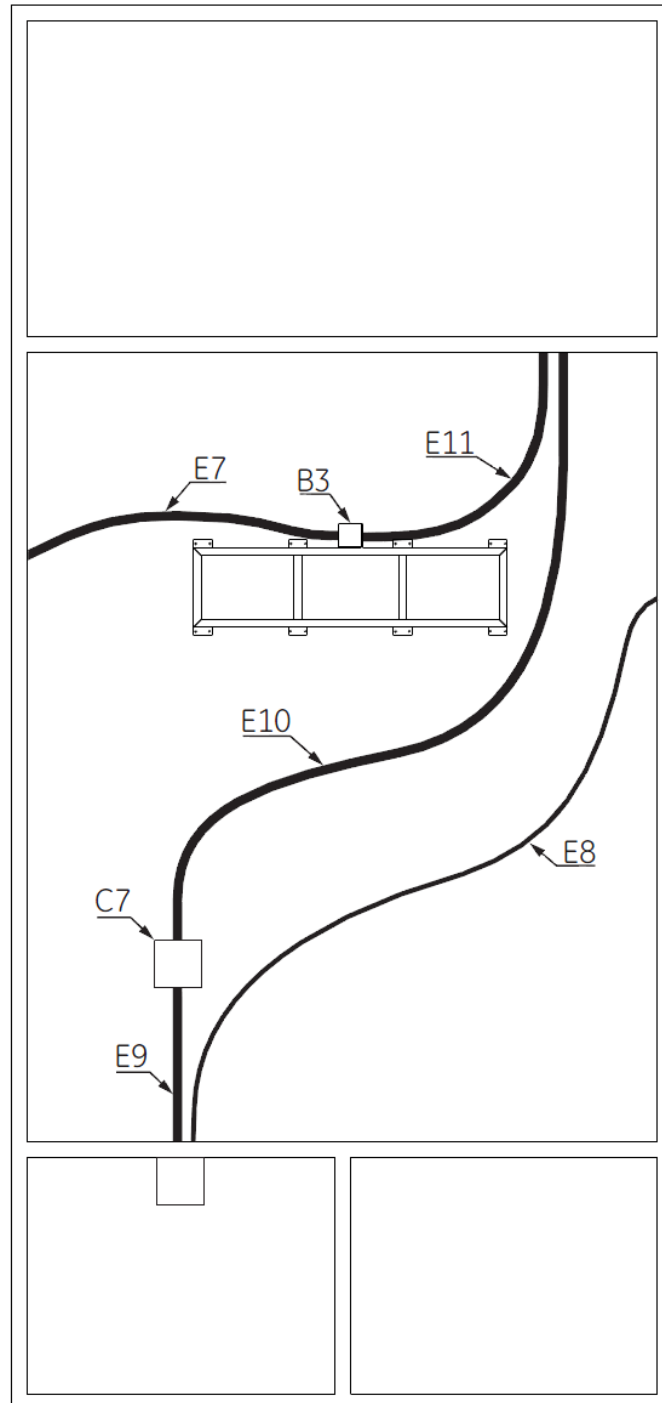




3.3.13 Arrangement of ceiling conduits

- The dimensions will be informed in the sketch.

Figure 3.3.13-1





3.3.14 Outlets and boxes on walls

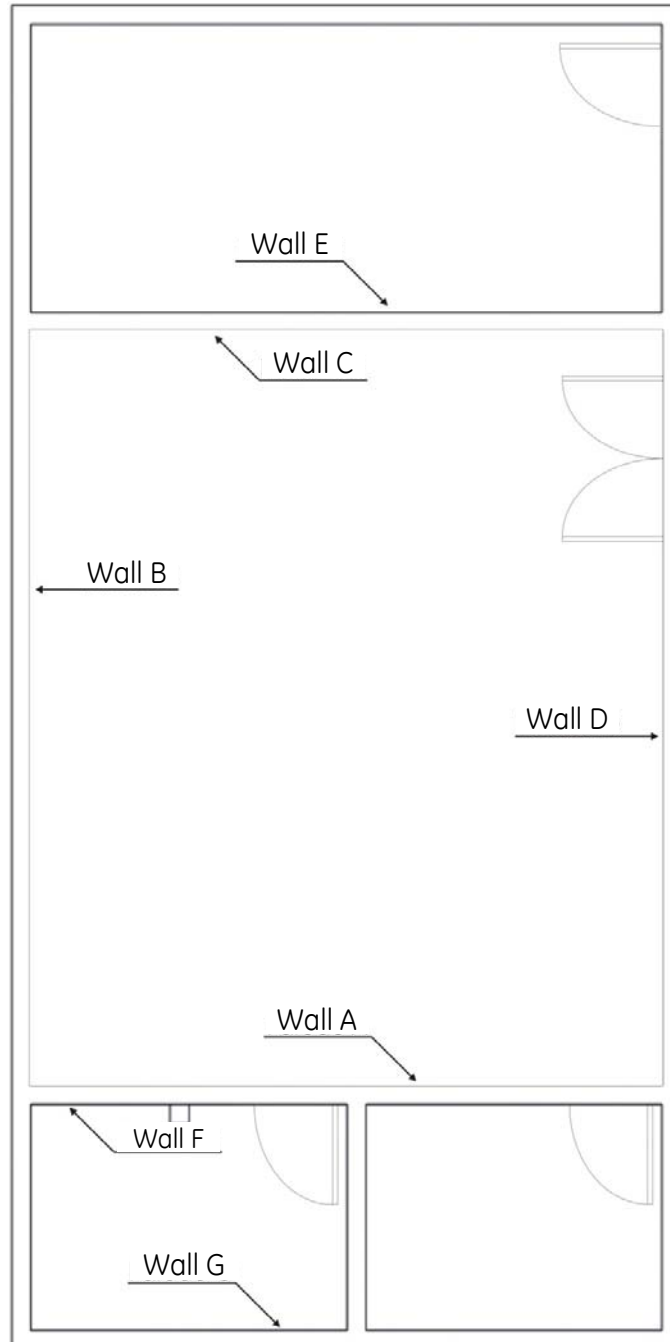
Table 3.3.14-1-Table of conduits and boxes

<i>Parameter</i>	<i>Gauge</i>	<i>Description</i>
E1	Conduit Ø75mm	connection arc base with the generator
E2	Conduit Ø75mm	connection of the generator with the control room
E3	Conduit Ø75mm	connection of the table base with the control room
E4	Conduit Ø75mm	connection between the boxes of the Table Base and Gantry B1 and B2
E5	Conduit Ø75mm	outtake of the cables of the magnetic switch for the PolluX supply
E6	Conduit Ø 3/4"	connection of polygraph with the floor box of the equipment room.
E7	Conduit Ø 50 mm	connection of the monitor with the polygraph, connected to the 4x4 box at 40 cm from the floor.
E8	Conduit Ø 3/4"	connection of the generator with the X-Ray signaling lamps.
E9	Conduit Ø 100 mm	for high voltage cables of the generator.
E10	Conduit Ø 75	input of power cables of the magnetic switch
E11	Conduit Ø 75	Connection of the monitor support to the control room
B1	Box 300x300x152mm	Standard box 300x300x152mm or similar Angix Gantry Base
B2	Box 300x300x152mm	Standard box 300x300x152mm or similar Angix Table Base
C1	Box 300x300mm	Box one
C2	Box 300x300mm	Box two
C7	Supplied by XPRO	Cable intake box, Arc C, ceiling
B3	Supplied by XPRO	Base of Monitor Support



3.3.15 Sockets and boxes on walls

Figure 3.3.15-1





3.3.16 Wall A

- Table head.

Figure 3.3.16-1

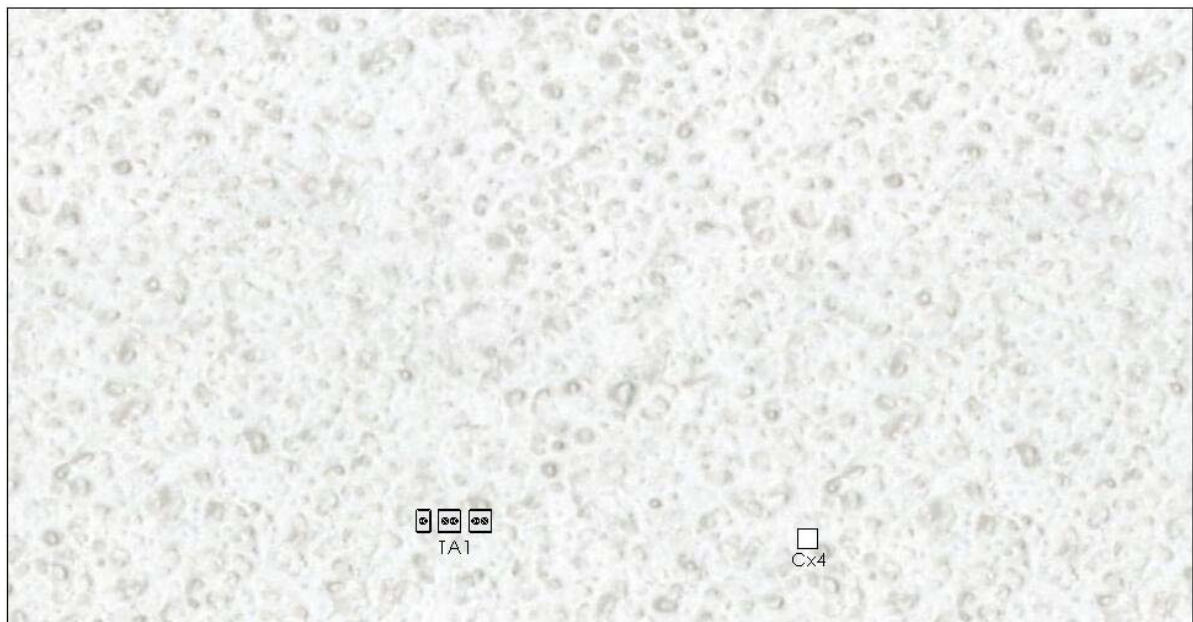




3.3.17 Wall B

- Left arm.

Figure 3.3.17-1





3.3.18 Wall C

- Table foot.

Figure 3.3.18-1

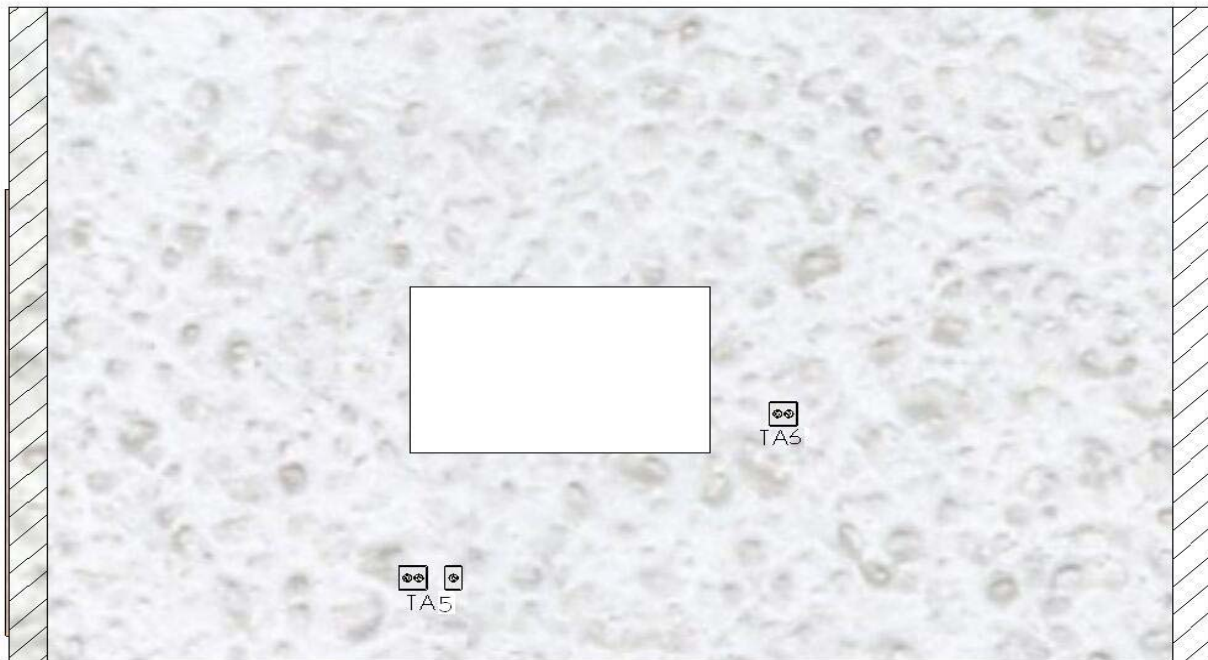




3.3.19 Wall E

- Internal wall of generator room.

Figure 3.3.19-1





3.3.20 Wall F

- Internal wall of generator room.

Figure 3.3.20-1

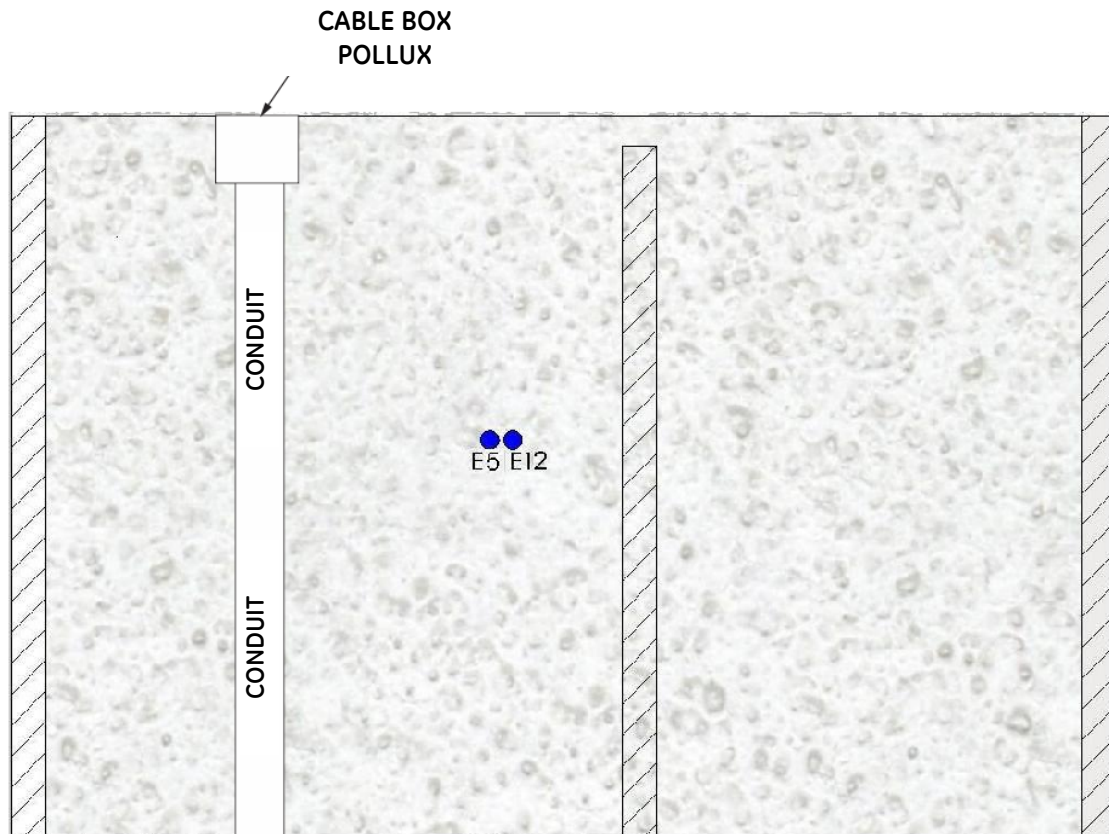




3.3.21 Wall G

- Internal wall of generator room. (Magnetic switch)

Figure 3.3.21-1



Conduits E5 and E12 are built into the wall.



XPRO recommends the installation of a perforated conduit on the wall, out of the Póllux cable box Figure 3.3.11-3, all the way to the floor, for a better organization of the cables in the equipment room.



- Figure 3.3.21-2 shows the lighting position pattern for the examination room.

Figure 3.3.21-2

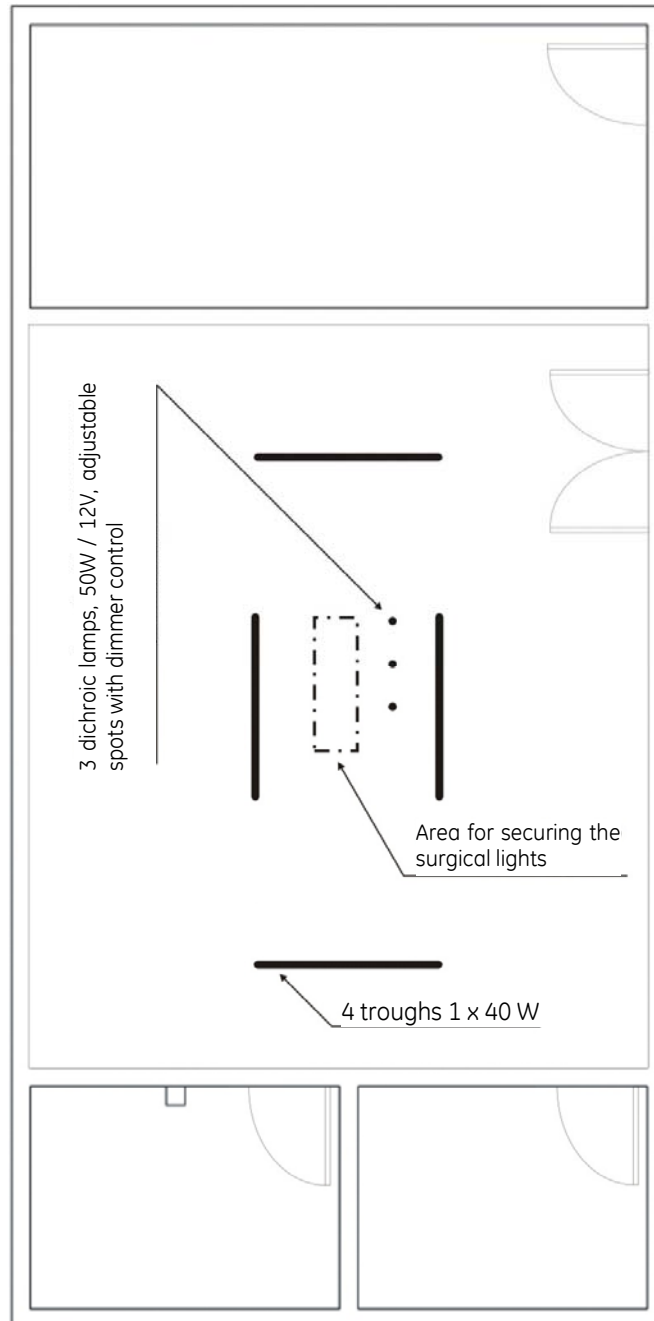




Table 3.3.21-1 – Sockets Table

Parameter	Size	Local Voltage, 127VAC	Local voltage, 220VAC
TA1	-	4 x 127 VAC + 1 x 220 VAC	5 x 220 VAC
TA2	-	TA2 3 X 127 VAC	3 x 220 VAC
TA3	-	TA3 3 X 127VAC + 1 X 220VAC	4 x 220 VAC
TA4	-	TA4 3 X 127VAC + 1 X 220VAC	4 x 220 VAC
TA5	-	TA5 3 X 127 VAC	3 x 220 VAC
TA6	-	TA6 3 X 127 VAC	3 x 220 VAC
TA7	-	TA7 2 X 127 VAC + 1 X NETWORK	2 x 220 VAC + 1 x NETWORK
TA8	-	TA8 1 X 127VAC	1 x 220VAC
TA9	-	TA9 1 X 127VAC	1 x 220VAC
CX1	Box 30x30	Behind the generator (position as of sketch, on floor or on room footer)	
CX2	Box 30x30	Acquisition and control cables (position as of sketch, on floor or on room footer)	
CX3	Box 4"x4" a 40 cm from the floor,	Póllux door lamp cabling	
CX4	Box 10x10x8 cm a 40 cm from the floor	Polygraph cabling (position as of sketch);	

3.3.22 Ceiling Depression

- The ceiling shall have a depression, as of Figure 3.3.13-1, in order to shelter the cable troughs and the monitor support base (if applicable). The interior faces of the monitor support base and the ceiling boxes shall be exposed, for the purposes of securing the support and cable hoses. The interior of the monitor support frame shall be sealed with the ceiling finish.



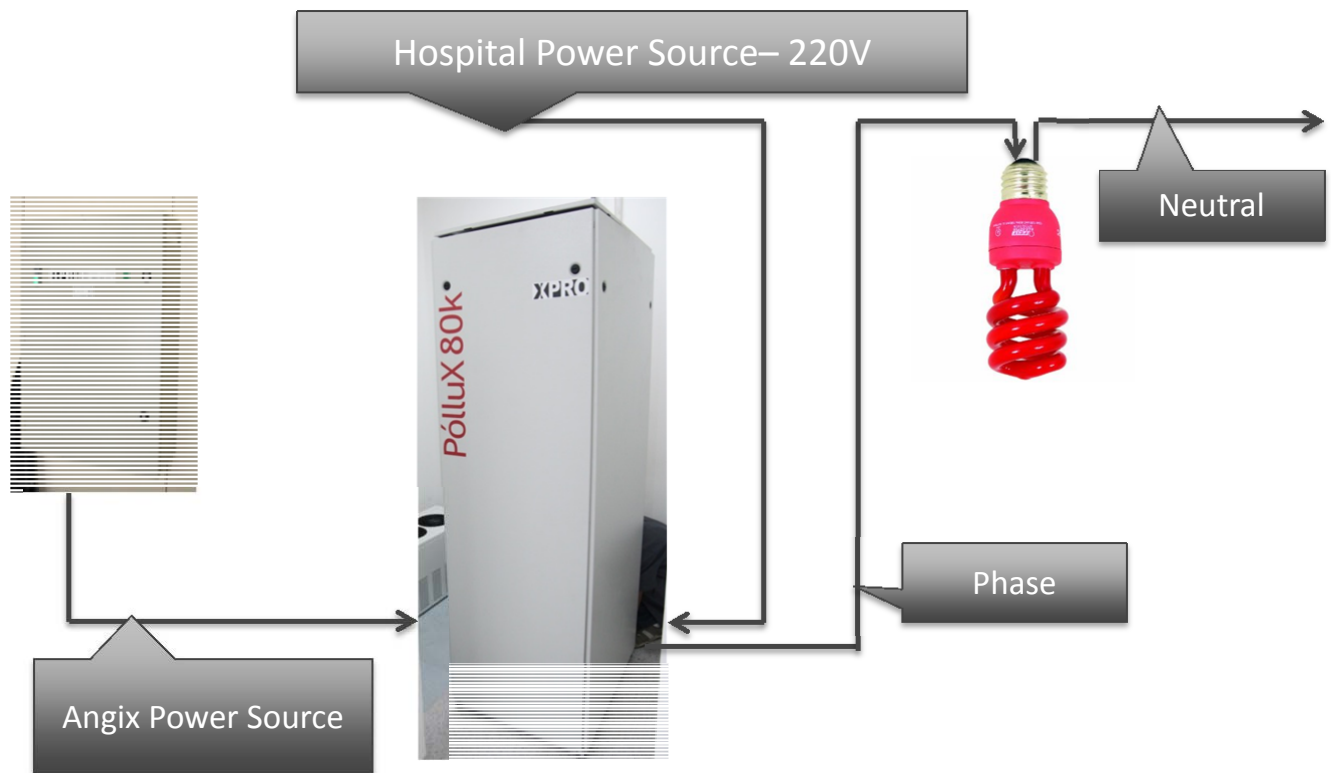
In case of doubts or exceptions regarding to the correct position, please get in touch with XPRO technical support service.

3.3.23 Signaling

- The internal symbol of the presence of ionizing radiation shall be affixed onto the door of main access to the X-ray room, restricting access to such area.
- A safety light indicating the equipment usage shall be installed at any point above the X-ray room access doors. Up to five lamps may be used, with connection as of Figure 3.3.23-1.



Figure 3.3.23-1



3.3.24 Air conditioning

- **Equipment Room:** 2 systems with com 18,000 BTU, one for backup in case of fault;
- **Procedures Room:** 2 systems of 18,000 BTU, one for backup in case of fault;
- **Control Room:** 2 systems with 12,000 BTU, one for backup in case of fault;
- Rooms with 30 m² shall have two equipment, of approximately 20,000 BTUs.
- The dimensioning is provided for ordinary operation with one equipment only, as to promote safety incase of fault to an operating equipment.
- Based on standard NBR 7256 – Air treatment in medical-assistance unit, the examination room shall have filtering for 4µm, air flow rate of 8m³/h and humidity control of 40% to 60%.
- Air conditioning devices must be positioned according to the sketch of installation provided by XPRO.
- The room of the Póllux generator must be maintained at 18°C.



3.3.25 Air dehumidifier

- For environments with up to 150 m³, use an air dehumidification device with capacity of up to 12 liters of water per day, with circulation of 500 m³/h.

3.3.26 Ceiling Height of the Examinations Room

- The maximum height of the ceiling height of the examination room is 2.80 meters, from the floor to the ceiling depression.



For other measurements, please get in touch with the XPRO technical support service.

3.4 Radiologic Protection

- For information purposes, a few suggestions are presented for room protection, which shall be evaluated and/or modified pursuant to the project of the responsible expert, based on Directive 453/98 – ANVISA – Ministry of Health:
- The doors of access to the X-Ray rooms shall be protected by lead sheets with 1.5 to 2 mm thick.
- Install lead glass or 80mm of common glass between the examination room and the control room.
- The walls shall be coated with barite mortar, according to the following procedures:
- Prepare the wall to be coated applying cement and sand roughcast, trace 1:2;
- Prepare the barite mortar with trace of 1 cement bucket, 4 buckets of thin wet sand and 1 bucket of barite (1:4: 1);
- The thickness of a coating with 2.5 to 3.0 cm is equivalent to 1.5 mm of lead;
- For the trace and thickness above, the consumption is of approximately 15 Kg/m².

3.5 Gas and vacuum spots

- Gas and vacuum must be provided next to the equipment.



For more details regarding to the correct position, please get in touch with XPRO technical support service.



3.6 Cleaning

- Observe the cleaning condition of the room for allocation of the Angix.



The room must be delivered for pre-installation visitation and for clean installation, with all conduits duly clear and dry.

3.7 Other considerations

- All holes of the equipment anchoring bases must be protected, as to avoid the entrance of dust, concrete and other particles that may compromise the installation.
- All floor conduits must be protected. The room must be delivered duly clean and with the conduits duly clear and dry.



Careful, any delays and problems in the installation due to the inobservance of the guidelines described herein are responsibility of the client.



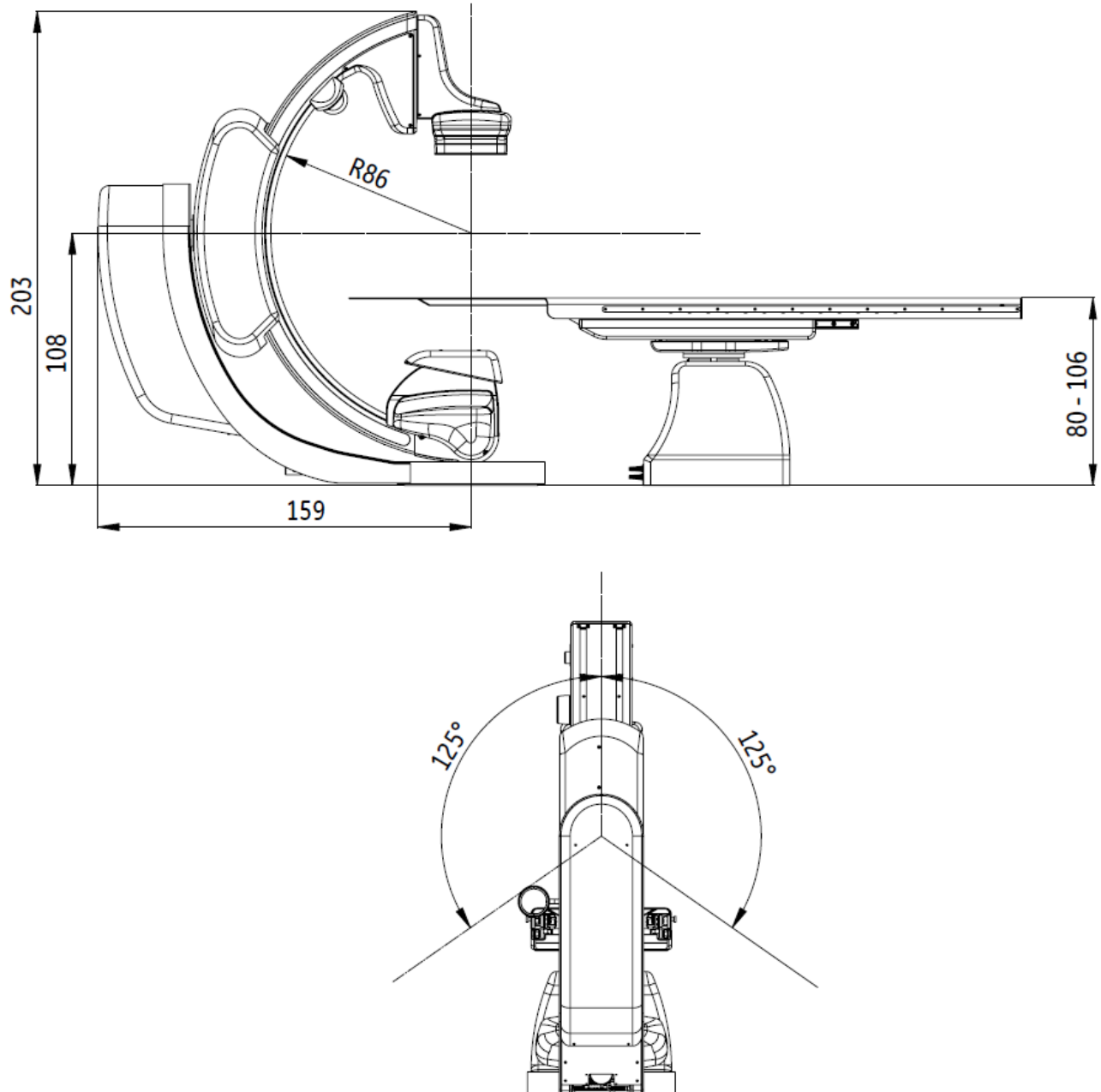
All floor and wall conduits must be built in.



4 EQUIPMENT DIMENSIONS

4.1 Angix III-FD

Figure 4.1-1



Note: Values in meters.



Figure 4.1-2

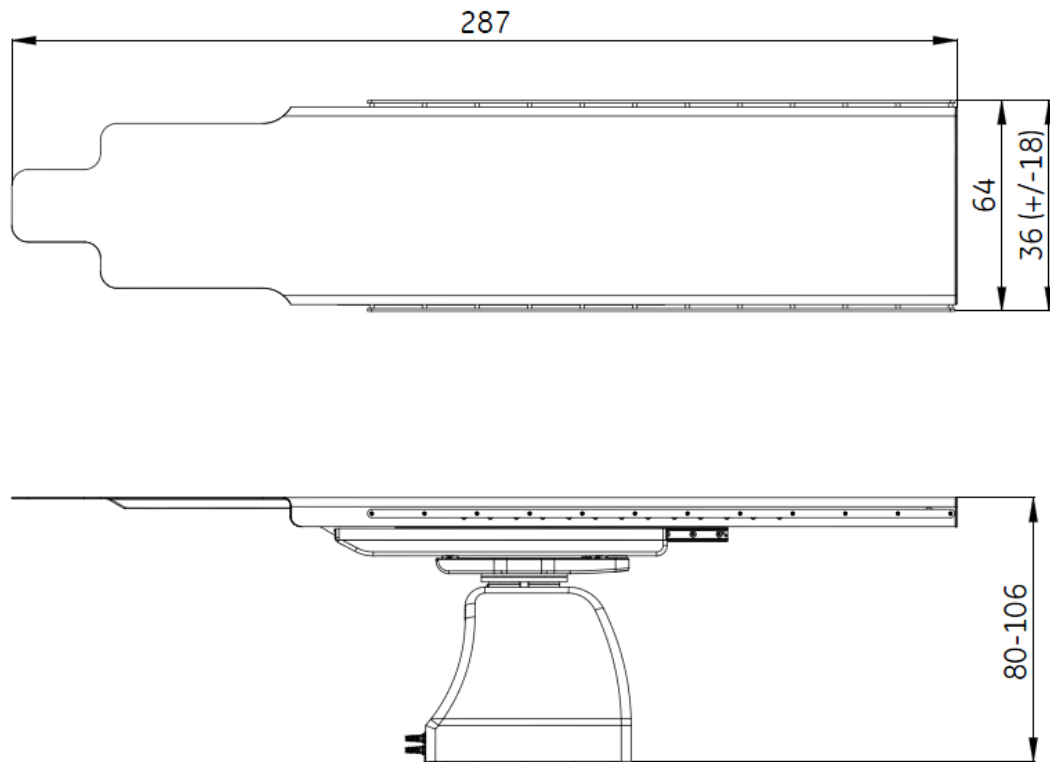
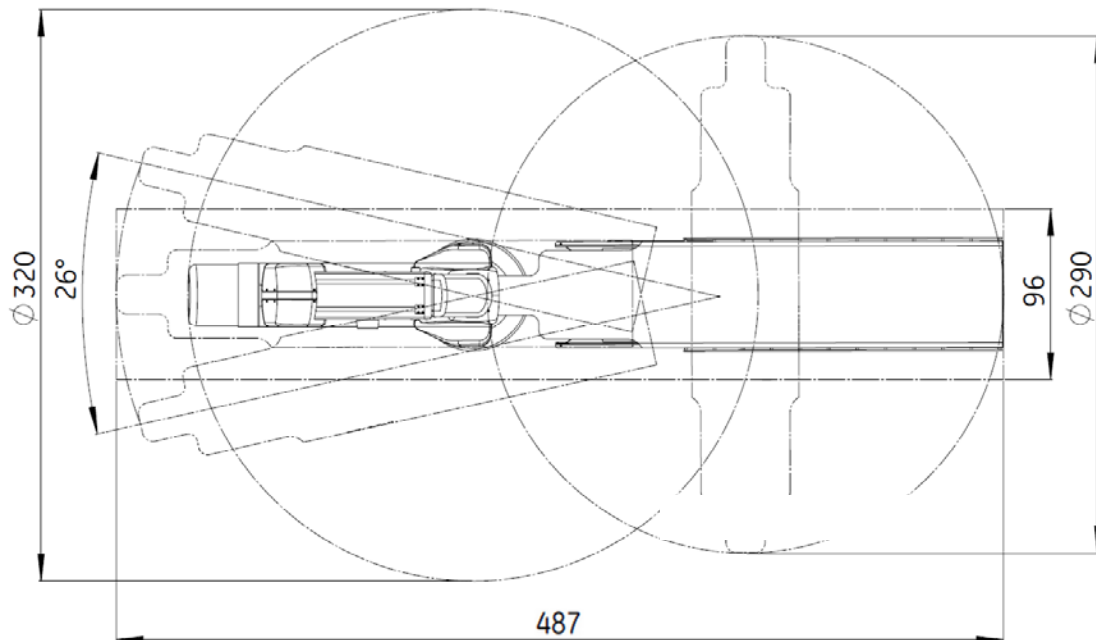


Figure 4.1-3

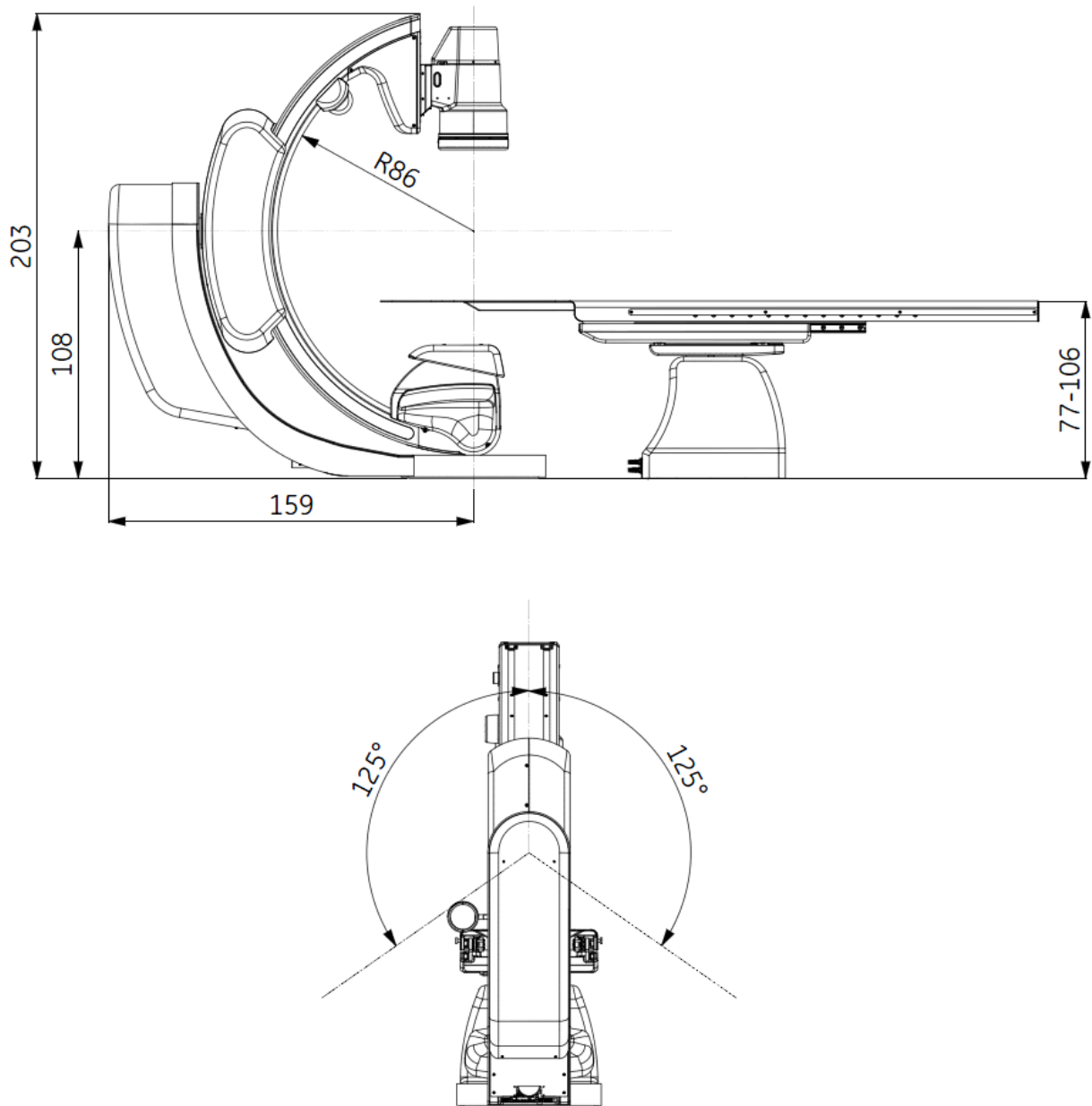


Note: Values in centimeters



4.2 Angix III-STD

Figure 4.2-1



Note: Values in centimeters



Figure 4.2-2

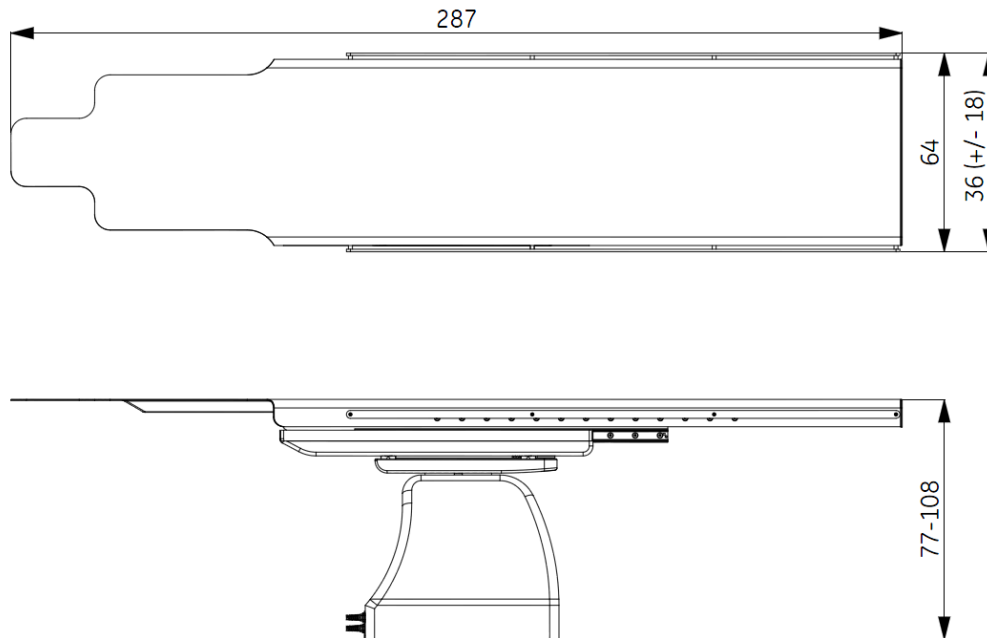
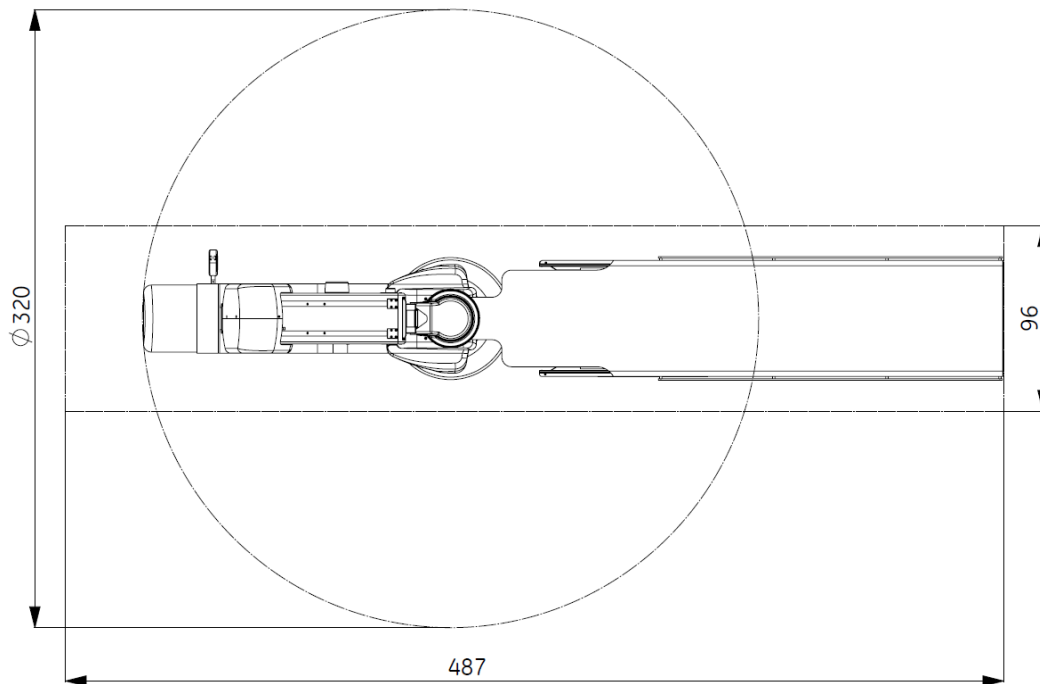


Figure 4.2-3



Note: Values in centimeters

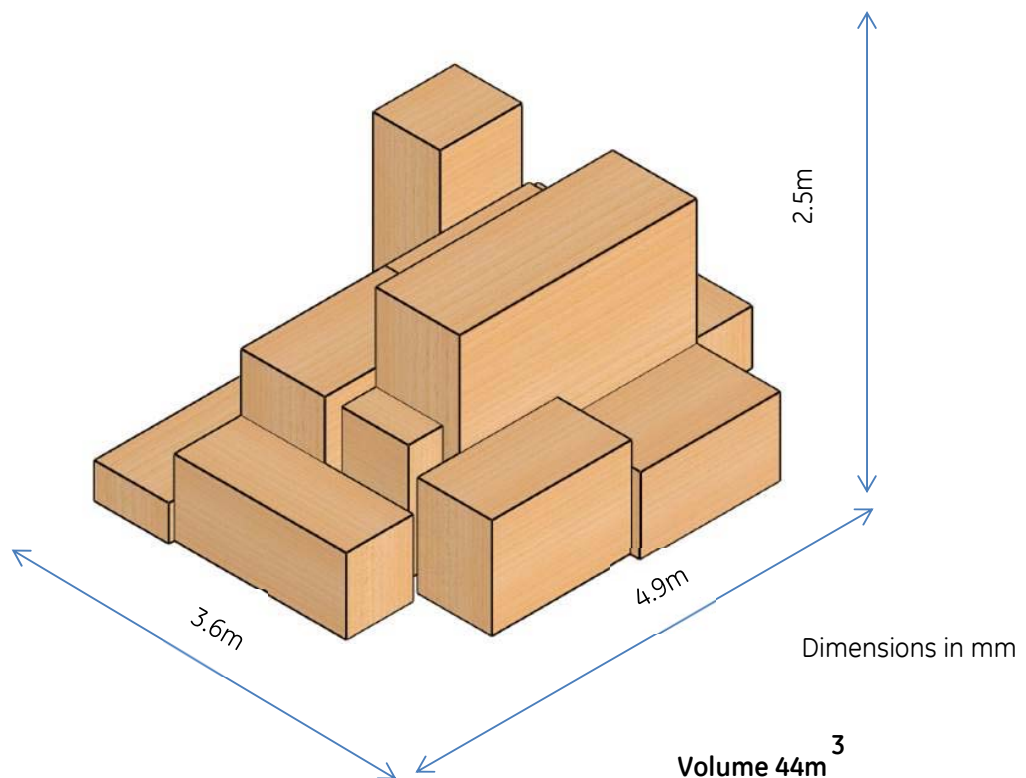


5 EQUIPMENT PACKAGES

5.1 Special care

- Packages must be maintained protected from humidity, rain, and splashing.
- The storage and handling positions are identified on the boxes, and can only be changed against the prior authorization by XPRO.
- Packages must be stored in the period of their receipt and start of the installation, inside the examination room already finished. The dimensions and volume required to storage the equipment, Figure 5.1-1.

Figure 5.1-1



Any damages caused to the equipment due to the inobservance of any of the aforementioned instruments are responsibility of the client, with XPRO being exempted from any culpability.



5.2 Dolly Curve Analysis

Check if the Gantry dolly can turn the corners and fit through the doorways, according to Figure and table 5.2-1.

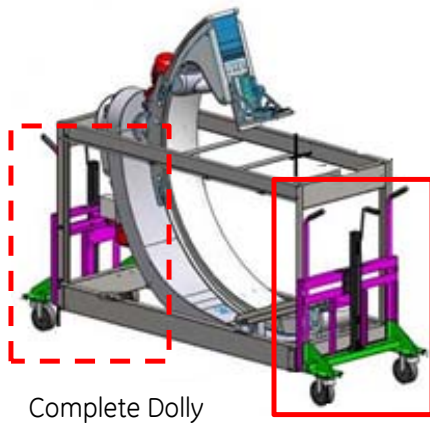


Figure 5.2-1

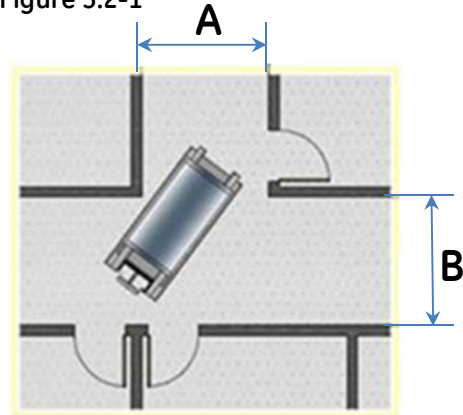


Table 5.2-1 – doorways dimensions

Complete Dolly (Width 850mm x length 2580mm)							
A (mm)	1134	1228	1323	1417	1512	1606	1700
B (mm)	2323	2112	1901	1795	1690	1584	1478

If there is a problem moving the support with the dolly attached, measure to see if it will make the turns with a shorter wheelbase, according to Figure and table 5.2-2.

Figure 5.2-2

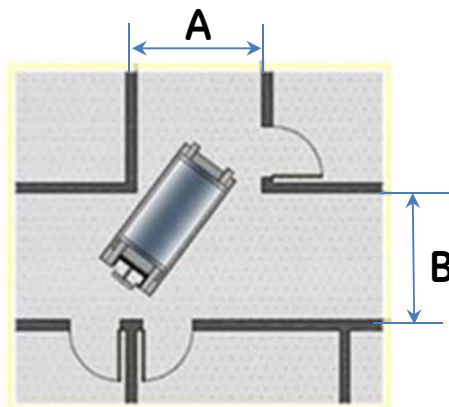
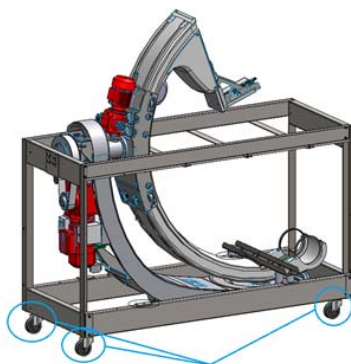


Table 5.2-2 doorways dimensions

Dolly Without support (Width 820mm x length 1990mm)							
A (mm)	1094	1185	1276	1367	1458	1549	1640
B (mm)	1792	1629	1466	1385	1303	1222	1140

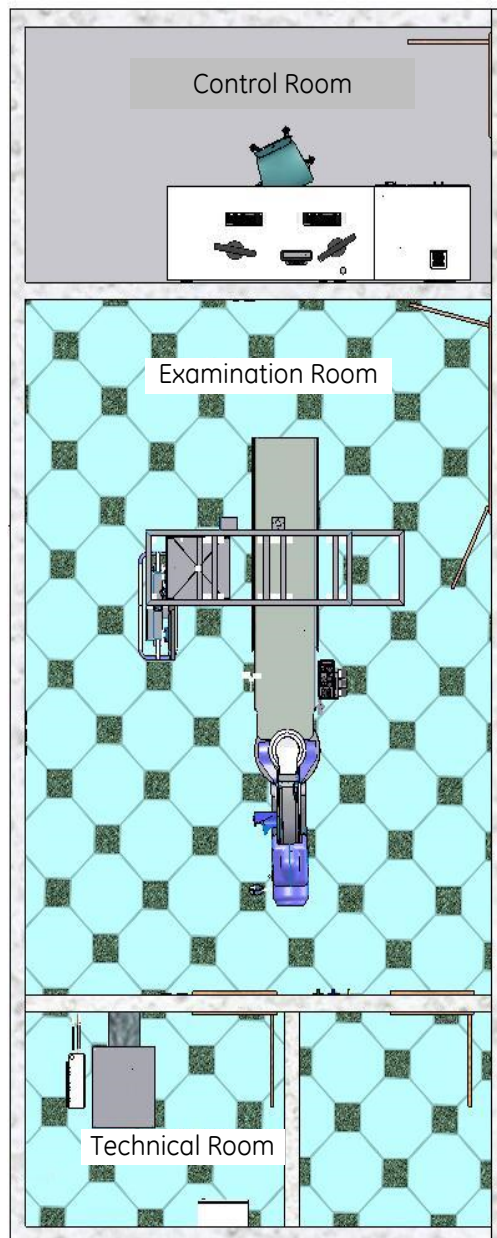


6 STANDARD PLANS

6.1 Layout of the Control Room and Examination Room

- Layout model for the Control Room and Examination Room, Figure 6.1-1.

Figure 6.1-1



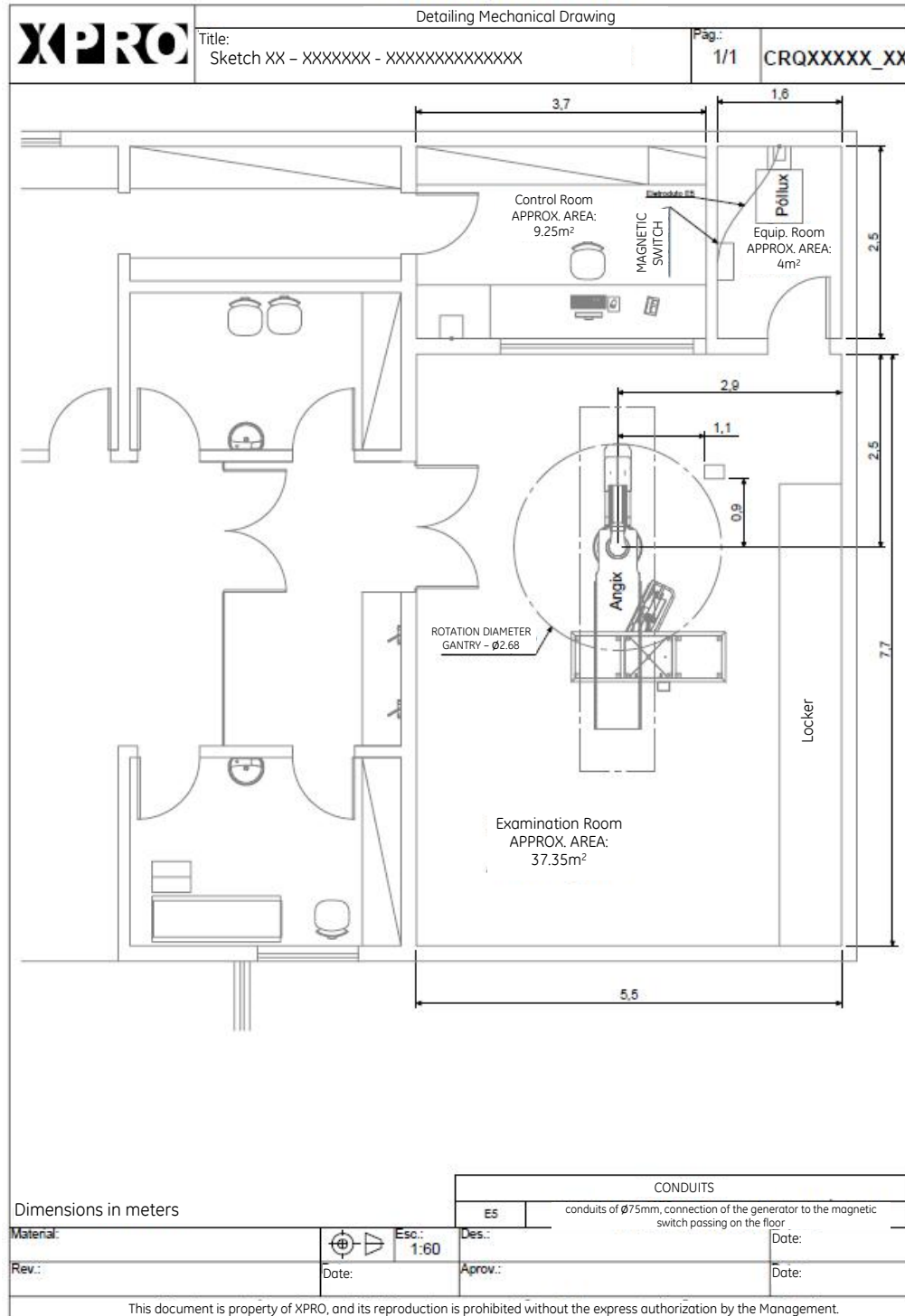
Note: Control room area as of Resolution RDC 50/2002 ANVISA.



6.2 Layout of the Hemodynamics Service

- Layout model for the Hemodynamics Service, as of

Figure 6.2-1.
Figure 6.2-1





7 MANUFACTURER / DISTRIBUTOR'S INFORMATION

Name:	XPRO Sistemas Ltda.
Operation Permit – ANVISA:	UXM109616W03
Address:	Av. Cristiano Machado 1989 Silveira - Belo Horizonte / MG CEP: 31.140-535
Telephone (technical support):	08007711225
Technician in Charge:	Marcos Rogério Bertoloni, Eng. CREA-MG 63399/D

7.1 Definitions

The definitions of the terms used in this document are provided below.

Table 7-1: Definitions

Term	Definition
NA	NA

7.2 Abbreviations

The abbreviations used in this document are presented below.

Table 7-2: Abbreviations

Abbreviation	Term
PMC	Mechanical Part
PNL	Panel
LOTO	Lock out – Tag out – Used for lock and identify of the power source.
CRQ	Sketch



8 RESPONSIBILITY AND REVIEW HISTORY

8.1 Document Responsibility

Engineering.

8.2 Authorization

Consult the *XMI* to obtain the approval signatures.

8.3 Review History

Table 8.3-1: Review History

REV	Page	Description of Changed Content	Justification for Changing	Author	Effective Date	Date of Periodical Review
1	NA	Initial release	Initial Release	Vinicius Silva	22/July/2015	-
2	NA	Including the Portuguese version on My Workshop	Portuguese version	Thiago Drumond	22/July/2015	-
Table of Change Impact						
Yes	No	N/A	Comments or Justifications if 'Not' for Validation or Training			
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Change to Formatting or Typo	First elaboration		
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Regulatory			
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Validation			
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Training			
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Communication			
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Labeling (List)			
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Other Documents (List)			
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Other (Describe)			